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Presidential Documents

Title 3—

The President

Proclamation 6423 of April 24, 1992

National Farm Safety Week, 1992

By the President of the United States of America

A Proclamation

The United States is no longer a primarily agrarian society, but we Americans still rely on our farmers and ranchers as heavily as we did more than 200 years ago. By helping to feed and to clothe millions of workers and their families, members of the agricultural industry have enabled this country to achieve the world's highest standards of health and productivity. In today's expanding global economy, which is creating opportunities to market an ever-wider array of agricultural products and by-products, our farmers and ranchers have an increasingly important role to play in promoting our Nation's competitiveness and strength. Because we depend on these enterprising individuals for our daily sustenance and for so much more, it is fitting that we set aside a special week to promote their health and safety.

Thanks in large part to public awareness campaigns such as National Farm Safety Week, we have made notable progress in our efforts to protect the lives and health of America's agricultural workers. According to the National Safety Council, a private, nonprofit organization that is dedicated to promoting public safety, the number of work-related deaths among agricultural workers has dropped over the past 10 years from an average of 54 per 100,000 to 42 per 100,000. The Council reports that nonoccupational accidents in rural areas have also decreased.

Despite such encouraging trends, however, far too many farmers and ranchers continue to suffer from injuries and illnesses that could be prevented. Improper and prolonged exposure to chemicals and environmental elements is having a harmful effect on the health of many agricultural workers and thus on their livelihood as well. Serious accidents are often the cruel price of carelessness and haste. The costs in human terms alone—which are far greater than the billions of dollars in lost productivity and medical expenses—warrant a strengthened commitment to improved safety measures and to healthier lifestyles.

The solutions are relatively simple and inexpensive, and they begin with the whole family. For example, farmers and ranchers can reduce their risk of developing dermatitis, lung disease, hearing loss, and other common occupational illnesses by wearing protective gloves, respirators, and ear plugs when the job calls for it. Empty pesticide containers should be disposed of safely, and leftover chemicals should be stored out of the reach of children. In addition to being given clear and consistent examples of prudence and caution—be it at work, on the road, or at play—youngsters should be taught the dangers of playing on or near farm machinery. Children should also be encouraged to recognize health hazards such as dust, noise, toxic fumes, and extreme exposure to the sun, and every member of every farm family should know what to do in the event of an emergency. Only when injury and illness prevention becomes a daily priority for all those who live and work on our Nation's farms and ranches can we reap a full harvest of better health and safety.

NOW, THEREFORE, I, GEORGE BUSH, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim the week of September 20 through September 26, 1992, as National Farm Safety Week. I urge all those who live and work on our Nation's farms and ranches to make health and safety an integral part of their daily activities. I call on organizations that serve agricultural workers and their families to sponsor or to support rural health and safety programs, and I encourage all Americans to observe this week with appropriate activities as an expression of our gratitude for the many contributions that men and women in agriculture make to our individual and collective well-being.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-fourth day of April, in the year of our Lord nineteen hundred and ninety-two, and of the Independence of the United States of America the two hundred and sixteenth.

George Bush

[FR Doc 92-10015
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Rules and Regulations

Federal Register
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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.
The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 213

RIN 3206-AE94

Schedule A Authority for Appointment of Former National Guard Technicians; Technical Amendment

AGENCY: Office of Personnel Management.
ACTION: Final regulations.

SUMMARY: The Office of Personnel Management (OPM) is amending the Schedule A excepted service appointing authority for certain National Guard Technicians who are receiving an annuity under the Civil Service Retirement System (CSRS) or the Federal Employees Retirement System (FERS) to update the statutory authority citation for those covered by FERS.

EFFECTIVE DATE: April 28, 1992.

FOR FURTHER INFORMATION CONTACT: Tracy E. Spencer (202) 606-0960 or FTS 266-0960.

SUPPLEMENTARY INFORMATION: Under 5 U.S.C. sections 8337(h), covering the Civil Service Retirement System (CSRS), and 8456, covering the Federal Employees Retirement System (FERS), National Guard Technicians appointed under 32 U.S.C. 709(a) may qualify for an annuity based on a disability that disqualifies them from membership in the National Guard or from holding a military grade required as a condition of their National Guard employment. Those sections further require that former National Guard Technicians receiving such annuities be afforded priority consideration for vacancies in their former commuting area at the same or equivalent grades as their former positions, and that the annuity be terminated if an individual either accepts such a position or declines a qualifying offer.

National Guard Technicians who are involuntarily separated without personal cause or misconduct have eligibility for noncompetitive appointment in the competitive service for 1 year following the involuntary separation. However, since the requirement for priority consideration continues without time limit, the Schedule A authority is needed to permit appointments after the first year.

Currently, the Schedule A authority refers to appointments of former National Guard Technicians who are receiving annuities under 5 U.S.C. 8337(h) or 8457. Those were the appropriate citations when the authority was established. However, recent revision of title 5, U.S. Code, has changed the FERS citation to 5 U.S.C. 8456. This technical amendment reflects that change.

E.O. 12291, Federal Regulation

I have determined that this is not a major rule as defined under section 1(b) of E.O. 12291, Federal Regulation.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because it affects only the procedures used to appoint certain Federal employees.

List of Subjects in 5 CFR Part 213

Government employees, Reporting and recordkeeping requirements.

Waiver of Notice of Proposed Rulemaking and 30-Day Delay of Effective Date

Under 5 U.S.C. 553(b)(3)(B) and (d)(3), I find that good cause exists for waiving the general notice of proposed rulemaking and for making the amendment effective in less than 30 days. The amendment merely reflects the current legal citation for a statutory provision that is already in effect.

Office of Personnel Management.
Constance Berry Newman,
Director.

Accordingly, OPM is amending 5 CFR part 213, as follows:

PART 213—EXCEPTED SERVICE

1. The authority citation for part 213 is revised to read as follows:

Authority: 5 U.S.C. 3301 and 3302, E.O. 10577, 19 FR 7521, 3 CFR, 1954-1958 Comp., p. 218; § 213.101 also issued under 5 U.S.C. 2103; § 213.102 also issued under 5 U.S.C. 1104, Pub. L. 95-454, sec. 3(5); § 213.3102 also issued under 5 U.S.C. 3301, 3302, 3307, 8337(h) and 8456; E.O. 12364, 47 FR 22931, 3 CFR 1982 Comp., p. 185.

2. In § 213.3102, paragraph (j) is revised to read as follows:

§ 213.3102 Entire executive civil service.

* * * * *

(j) Positions filled by: (1) Appointment of persons previously employed as National Guard Technicians under 32 U.S.C. 709(a) in positions at the same or equivalent grade level, or below, who are applying for or receiving an annuity under the provisions of 5 U.S.C. 8337(h) or 5 U.S.C. 8456 by reason of a disability that disqualifies them from membership in the National Guard or from holding the military grade required as a condition of their National Guard employment; or (2) reassignment, promotion or demotion within the same agency of former National Guard Technicians originally appointed under this authority.

* * * * *

[FR Doc. 92-9756 Filed 4-27-92; 8:45 am]
BILLING CODE 6325-01-M

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 337

RIN 3064-ABOO

Unsafe and Unsound Banking Practices

AGENCY: Federal Deposit Insurance Corporation ("FDIC").
ACTION: Final rule.

SUMMARY: The FDIC is amending its regulations on extensions of credit by insured nonmember banks to their executive officers to allow insured nonmember banks to make extensions of credit to such officers for any purpose other than the education of their children or the financing of their residence (*i.e.*, other purpose loans) up to the higher of 2.5 percent of the bank's capital and unimpaired surplus or $25,000; provided however, that in no event may such extensions of credit exceed $100,000.

EFFECTIVE DATE: May 28, 1992.

FOR FURTHER INFORMATION CONTACT: Pamela E.F. LeCren, Counsel (202) 898-3730, Legal Division, FDIC, 550 17th Street, NW., Washington, DC 20249 or Michael D. Jenkins, Examination Specialist, (202) 898-6896, Division of Supervision, FDIC, 550 17th Street, NW., Washington, DC 20429.

SUPPLEMENTARY INFORMATION:

Background

On December 19, 1991 President Bush signed into law the Federal Deposit Insurance Corporation Improvement Act of 1991 ("FDICIA", Pub. L. No. 102-242, 105 Stat. 2236). Section 306 of FDICIA, among other things, amended section 18(j)(2) of the Federal Deposit Insurance Corporation Act ("FDI Act", 12 U.S.C. 1828(j)(2)) to provide that section 22(g) of the Federal Reserve Act (12 U.S.C. 375a) "shall apply with respect to every nonmember insured bank in the same manner and to the same extent as if the nonmember insured bank were a member bank". The amendments made by section 306 of FDICIA do not become effective until the earlier of the day regulations adopted by the Board of Governors of the Federal Reserve System ("Federal Reserve Board") implementing section 306 become effective or 150 days from the enactment of section 306 (May 18, 1992). Section 306(m)(2) of FDICIA directs the FDIC to adopt regulations no later than 120 days after December 19, 1991 implementing section 22(g)(4) which, as more fully described below, allows the FDIC to set by regulation the maximum amount of loans other than education and mortgage loans that an insured nonmember bank may make to its executive officers. A description of section 22(g) follows.

Section 22(g) of the Federal Reserve Act prohibits member banks from making extensions of credit to their executive officers except to the extent authorized therein. It requires that extensions of credit by a member bank to its executive officers be promptly reported to the bank's board of directors and that extensions of credit to executive officers only be made if the bank would be authorized to make the extension to other borrowers, the extension of credit is on terms not more favorable than those afforded other borrowers, the executive officer has submitted a detailed current financial statement, and the extension of credit is made on the condition that it becomes due and payable on demand at the option of the bank if the executive officer becomes indebted to any other bank or banks in an amount that could not be extended to such officer by his/her own bank. It requires executive officers to make a report to the bank's board of directors if the executive officer becomes indebted to another bank in an amount in excess of that which the member bank could extend to the officer and requires member banks to include along with their report of condition a report of all loans made by the bank to its executive officers since the submission of its last call report. The report to the board of directors must indicate the date and amount of each extension of credit, the security therefor, and the purposes for which the proceeds were used. With the exception noted below, the Federal Reserve Board is given the authority to write regulations implementing section 22(g). By operation of law, those regulations apply to insured nonmember banks. (See 57 FR 7647, March 4, 1992 which contains a final amendment to part 337 of the FDIC's regulations that makes the necessary conforming amendments to part 337.)

Section 22(g) specifically provides that member banks may extend credit to an executive officer of the bank if the loan is secured by a first lien on a dwelling to be owned by the executive officer and used as the executive officer's residence provided that no other such mortgage loan is outstanding to the executive officer. Member banks may also extend credit to an executive officer for the purpose of financing the education of the officer's children. Other types of loans may be made to the extent permitted by regulation. Section 22(g)(4) provides that extensions of credit to an executive officer not otherwise specifically authorized by section 22(g) may be made "in an amount prescribed in a regulation of the member bank's appropriate Federal banking agency". Loans may be made to a partnership in which one or more of the bank's executive officers are partners and have either individually or together a majority interest provided that the loans do not exceed the limit set by the appropriate agency pursuant to section 22(g)(4). The total amount of credit extended by a member bank to such partnership is considered to be extended to each executive officer of the member bank who is a member of the partnership. (See section 22(g)(5).)

On March 4, 1992 the FDIC published for comment a proposed amendment to part 337 setting out the amount of "other purpose loans" an insured nonmember bank may make. (57 FR 7669, March 4, 1992.) The description of the proposal as contained in the **Federal Register** notice accompanying the proposed amendment is republished below.

Description of Proposal

As set forth above, the FDIC is authorized to establish by regulation the amount of loans an insured nonmember bank may make to its executive officers under section 22(g)(4) of the Federal Reserve Act. Member banks have been subject to the limitations of section 22(g)(4) for several years. The relevant limit as to member banks regarding loans to executive officers for purposes other than education and home mortgages is set out in § 215.5(c)(3) of the Federal Reserve Board's Regulation O (12 CFR 215.5(c)(3)). Section 215(b) of Regulation O contains a cross reference to § 215.5(c)(3) and indicates that a member bank may not extend credit to a partnership in which one or more of its executive officers are partners in an aggregate amount greater than that permitted by § 215.5(c)(3). Section 215.5(b) implements section 22(g)(5) of the Federal Reserve Act which, like the remainder of section 22(g), is now applicable to insured nonmember banks.

Section 215.5(c)(3) of Regulation O provides that the total amount of any loans made to an executive officer (other than for the purpose of educating the officer's children or financing the purchase, construction, maintenance, or improvement of the officer's residence) may not exceed the higher of 2.5 percent of the bank's unimpaired capital and surplus (as that term is defined in Regulation O) or $25,000, but in no event may such loans exceed $100,000. Inasmuch as state member banks and national banks are subject to the limits on loans as set forth in § 215.5(c)(3) of Regulation O and the FDIC saw little purpose to be served by adopting a different limit for insured nonmember banks now that section 22(g) was made applicable to such institutions, the FDIC proposed to subject insured nonmember banks to the same limit. To do so will avoid creating any disparity of treatment among banks based upon their membership, or lack of membership, in the Federal Reserve System.

Interaction of Proposed Regulation With Other Lending Limits Under Section 22(h) of Federal Reserve Act

Pursuant to section 22(h) of the Federal Reserve Act and section 18(j)(2) of the FDI Act, an insured nonmember bank is prohibited from making extensions of credit to any of its executive officers and their related interests in an amount in excess of the limit on loans to a single borrower

established by section 5200 of the Revised Statutes. (12 U.S.C. 84.) That limit is generally 15 percent of the bank's capital and unimpaired surplus in the case of loans that are not fully secured, with an additional 10 percent allowable in the case of loans that are fully secured by readily marketable collateral having a market value determined by reliable and continuously available price quotations. As a result of the statutory changes enacted by FDICIA and the regulatory amendment proposed herein, insured nonmember banks will be further limited when lending to their executive officers if the loans are for a purpose other than the education of the officers' children or the financing of the officers' home. In no event may such "other" purpose loans exceed an aggregate amount of $100,000. Therefore, even though section 22(h) and the FDIC's regulations would allow an insured nonmember bank to extend credit to an executive officer and his or her related interest in an amount equal to 15 percent of the bank's capital and unimpaired surplus, if such amount is greater than $100,000 and the loan in question is for a purpose other than the education of the officer's children or the financing of the officer's residence, the loan to an executive officer may not exceed a maximum of $100,000. If the higher of 2.5 percent of the bank's capital and unimpaired surplus (as that term is defined in Regulation O) or $25,000 is lower than $100,000, the figure that is lower than $100,000 becomes the ceiling on the loan amount. Insured nonmember banks should keep in mind that the $100,000 limit (or whatever lower figure that may be applicable) is an aggregate limit for all "other" purpose loans.

Effect of Proposal, if Finalized, on Outstanding Extensions of Credit

Under the proposed amendment, any outstanding extension of credit to an executive officer that, if made after the effective date of the regulation, would have been in violation of the lending limit established under the proposal is treated in one of two ways. If the extension of credit has a specific maturity date one year or later from the effective date of the amendment, the extension of credit must be repaid according to the payment schedule that was in existence prior to the date the amendment becomes effective. If the extension of credit does not have a specific maturity date one year or later from the effective date of the regulation, any renewal or extension of the extension of credit must be made on terms that will bring the extension of credit into compliance with the lending limit contained in § 337.3(c)(1) and (c)(2) by no later than one year from the date the amendment becomes effective. The proposal thus provided an insured nonmember bank one year to bring into compliance outstanding extensions of credit which fall within the second category that exceed the limits of § 337.3(c)(1) or (c)(2). Thus, an extension of credit that is due before the end of the one year period beginning on the effective date of the amendment may be renewed or extended during the first year after the effective date regardless of the limit contained in § 337.3(c) so long as the extension of credit is brought into compliance within one year. If an insured nonmember bank is unable to bring all extensions of credit outstanding on the effective date of the regulation into compliance with required, the compliance date may be extended for good cause shown for not more than two additional one-year periods.

The compliance period provided for under the proposal is essentially the same that was given insured nonmember banks to bring outstanding extensions of credit into compliance with section 22(h) and Regulation O when it was originally adopted. (See 12 CFR 215.6, 1979).

Comment Summary

The FDIC received 62 comments in response to the proposal. The majority of the comments objected to limiting "other purpose" loans to executive officers to the higher of 2.5% of capital and unimpaired surplus or $25,000 but in no event higher than $100,000. The limit was criticized for several reasons. It was seen as unjustly discriminating against executive officers as compared to other insiders of the bank or other borrowers; as having a disproportionate adverse impact on small community and rural banks; and as critically impairing the ability of executive officers to finance their personal businesses. Several commenters objected to having any additional limit on loans to executive officers as such loans are already subject to intense scrutiny. Six commenters thought that the limit would make it more difficult to attract directors. One commenter indicated that he recognized the need for uniformity in the limit as between nonmember banks and member banks but urged the FDIC as well as the other federal banking agencies to consider raising the limit at some time in the near future. One comment expressed the opinion that loans secured by a residence and used for something other than the financing, purchase, construction, maintenance or improvement of the officer's residence should not be placed in the "other purpose" loan category.

It was suggested that the FDIC: (1) Not adopt any additional limit on "other purpose" loans in which case such loans would simply count toward the 15 percent and 10 percent of capital and unimpaired surplus limit that already applies to executive officer loans; (2) adopt a limit of 10 percent of capital and unimpaired surplus; (3) adopt a limit of 25 percent of capital and surplus if the loans are fully secured; (4) adopt a maximum limit of $200,000; (5) adopt a maximum limit of $150,000 or in the alternative $140,000 with an annual adjustment for inflation; (6) adopt a maximum limit of $500,000; or (7) except from the $100,000 limit any loans secured by certificates of deposits held by the bank, loans secured by government obligations, and any loans guaranteed by the federal government. One commenter applauded the proposed limit and urged the FDIC to extend it to directors and principal shareholders as well as executive officers. Another commenter supported the proposed limit precisely because it removes the unequal treatment of member and nonmember banks. Only one of the comments addressed the proposed compliance phase-in period. That comment applauded the proposed phase-in.

One of the comments requested that the FDIC clarify the definition of "executive officer" for the purposes of § 337.3(c) as proposed. The comment pointed out that a footnote to § 215.5(a) of Regulation O indicates that for the purposes of complying with the provisions of Regulation O implementing section 22(g) of the Federal Reserve Act the term "executive officer" does not include an executive officer of the bank's holding company or any other subsidiary of that holding company. Thus, member banks do not consider such persons to be executive officers when complying with the "other purpose" loan limitations found in § 215.5. In the commenter's opinion, an ambiguity will be created if the FDIC adopts the proposal as worded. If this point is not clarified, in the commenter's opinion one could read the proposal as subjecting a larger group of persons to the "other purpose" loan limits in the case of insured nonmember banks than member banks. In the same vein, the FDIC received an oral comment from a banker indicating that if the FDIC does adopt a limit on "other purpose" loans, the regulation should clarify that the limit as set out in § 337.3(c) of the regulation applies for the purposes of complying with § 215.5(d) of Regulation

O rather than the limit on "other purpose" loans as set out in § 215.5(c) of Regulation O. Section 215.5(d), which was made applicable to insured nonmember banks by the FDIC's recent final amendment to § 337.3 of the FDIC's regulations, requires that extensions of credit to executive officers be made subject to the condition that they become due and payable at any time the officer becomes indebted to another bank in an aggregate amount exceeding that which is permissible under § 215.5(c) of Regulation O.

Analysis of Comments and Changes to Regulation

After carefully reviewing the comments the FDIC has determined to adopt the limit on "other purpose" loans as proposed and to adopt the compliance phase-in period without any amendments. Language is being added, however, in § 337.3(c)(5) addressing the two points the FDIC was asked to clarify.

The FDIC does not feel that the law allows the agency to do away with the "other purpose" loan limits entirely. Furthermore, it is still the FDIC's opinion that it is appropriate to put nonmember banks and member banks on a par as to the "other purpose" loan lending limit. Congress was aware that loans to insiders, including executive officers, are subject to close scrutiny under section 22(h) of the Federal Reserve Act. Rather than eliminate the additional restriction on loans to executive officers that was already applicable to member banks, Congress chose to make that restriction applicable to nonmember banks as well. Member banks have been subject to limit since 1983. If these institutions have been able to comply and neither the Federal Reserve Board or the Comptroller of the Currency has seen to alter the limit, it would be inappropriate for the FDIC to create a disparity of treatment among member and nonmember banks.

The FDIC is of the opinion that the "other purpose" loan limit will not have as harsh an impact as expected by the commenters. Insured nonmember banks that commented on the adverse impact the limit would have on a bank's business relationship with its executive officers should note that the "other purpose" loan limits contained in § 337.3(c) only apply to loans made to executive officers and to partnerships in which one or more of the bank's executive officers hold a majority interest. The limit does not encompass all entities that may be "related interests" as that term is used for purposes of § 337.3. Thus, loans to a company (other than a partnership) controlled by an executive officer, will be subject to the general loan to bank insider limits, *i.e.*, 15 percent of capital and unimpaired surplus with an additional 10 percent if the additional loan amount is fully secured by readily marketable collateral. Commenters who expressed concern that the proposed limit will make it harder for banks to attract directors should note that the limit only applies to executive officers. Finally, not including loans secured by a residence as a "home loan" if the purpose of the loan was for something other than the financing, purchase, construction, maintenance or improvement of that residence does not go beyond the statute's mandate. Section 22(g) of the Federal Reserve Act specifically allows mortgage loans to execute officers if the loan is secured by a dwelling and "it is expected, *after the making of the loan*, (that the dwelling will) be owned by the officer". The statute thus itself narrowly defines what falls within the mortgage loan category and not the "other purpose" loan category.

Regulatory Flexibility Act

It is the opinion of the Board of Directors that the final amendment will not have a differential adverse impact on small banks. Compliance will not necessitate the development of sophisticated recordkeeping or reporting systems by small institutions nor the expertise of specialized staff accountants, lawyers, or managers who would have to be retained by small institutions. In fact, small institutions may find compliance easier and less costly than larger institutions as small institutions can be expected to have fewer executive officers. The Board of Directors therefore hereby certifies, pursuant to section 605 of the Regulatory Flexibility Act (12 U.S.C. 605), that the final amendment will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 12 CFR Part 337

Banks, Banking, Reporting and recordkeeping requirements, Securities.

In consideration of the foregoing, the FDIC hereby amends part 337 of title 12 of the Code of Federal Regulations as follows:

PART 337—UNSAFE AND UNSOUND BANKING PRACTICES

1. The authority citation for part 337 is revised to read as follows:

Authority: 12 U.S.C. 1816, 1818(a), 1818(b), 1819, 1821(f), 1828(j)(2), 1831f, 375a(4), 375b.

2. Section 337.3 is amended by adding a new paragraph (c) to read as follows:

§ 337.3 Limits on extensions of credit to executive officers, directors, and principal shareholders of insured nonmember banks.

* * * * *

(c)(1) No insured nonmember bank may extend credit in an aggregate amount greater than the amount permitted in paragraph (c)(2) of this section to a partnership in which one or more of the bank's executive officers are partners and, either individually or together, hold a majority interest. For the purposes of paragraph (c)(2) of this section, the total amount of credit extended by an insured nonmember bank to such partnership is considered to be extended to each executive officer of the insured nonmember bank who is a member of the partnership.

(2) An insured nonmember bank is authorized to extend credit to any executive officer of the bank for any other purpose not specified in § 215.5(c)(1) and (2) of Federal Reserve Board Regulation O if the aggregate amount of such other extensions of credit does not exceed at any one time the higher of 2.5 percent of the bank's capital and unimpaired surplus or $25,000 but in no event more than $100,000.

(3) Any extension of credit that was outstanding on May 28, 1992 and that would if made on or after that date violate paragraph (c)(1) or paragraph (c)(2) of this § 337.3 shall be reduced in amount by May 28, 1993 so that the extension of credit is in compliance with the lending limit set forth in paragraphs (c)(1) and (c)(2) of this section. Any renewal or extension of such an extension of credit on or after May 28, 1992 shall be made only on terms that will bring the extension of credit into compliance with the lending limit of paragraphs (c)(1) and (c)(2) of this section by May 28, 1993, however, any extension of credit made before May 28, 1992 that bears a specific maturity date of May 28, 1993 or later shall be repaid in accordance with its repayment schedule in existence on or before May 28, 1992.

(4) If an insured nonmember bank is unable to bring all extensions of credit outstanding as of May 28, 1992 into compliance as required by paragraph (c)(3) of this § 337.3, the bank may at the discretion of the appropriate FDIC regional director (Division of Supervision) obtain, for good cause shown, not more than two additional one-year periods to come into compliance.

(5) For the purposes of paragraph (c) of this section, the definitions of the

terms used in Federal Reserve Board Regulation O shall apply including the exclusion of executive officers of a bank's parent bank holding company and executive officers of any other subsidiary of that bank holding company from the definition of executive officer for the purposes of complying with the loan restrictions contained in section 22(g) of the Federal Reserve Act. For the purposes of complying with § 215.5(d) of Federal Reserve Board Regulation O, the reference to "the amount specified for a category of credit in paragraph (c) of this section" shall be understood to refer to the amount specified in paragraph (c)(2) of this § 337.3.

By order of the Board of Directors.

Dated at Washington, DC, this 21st day of April 1992.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[FR Doc. 92-9754 Filed 4-27-92; 8:45 am]

BILLING CODE 6714-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 91-NM-218-AD; Amendment 39-8227; AD 92-09-02]

Airworthiness Directives; Boeing Model 737-100 and 737-200 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to all Boeing Model 737 series airplanes, that currently requires periodic inspections of the fuel lines contained within the wing fuel tanks to detect air leakage. The requirements of that AD are intended to detect air leakage into the fuel feed lines during fuel system suction feed operation at low fuel levels, which could result in simultaneous unrecoverable loss of power of both engines. This amendment limits the applicability of the AD to only Boeing Model 737-100 and 737-200 series airplanes, line number 001 through line number 900. This amendment is prompted by a determination that design features incorporated in later models of this airplane series have eliminated the leakage problem and thereby make the periodic inspections unnecessary.

DATES: Effective June 2, 1992.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of June 2, 1992.

ADDRESSES: The service information referenced in this AD may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue SW., Renton, Washington; or at the Office of the Federal Register, 1100 L Street NW., room 8401, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Bray, Seattle Aircraft Certification Office, Propulsion Branch, ANM-140S, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (206) 227-2681; fax (206) 227-1181.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations by superseding AD 84-03-01, Amendment 39-4803 (49 FR 5056, February 10, 1984), which is applicable to all Boeing Model 737 series airplanes, was published in the **Federal Register** on December 10, 1991 (56 FR 64486). The action proposed to limit the applicability of the existing AD to only Boeing Model 737-100 and 737-200 series airplanes, line number 001 through line number 900.

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

Two commenters support the rule as proposed.

A third commenter also supports the rule as proposed, but does point out a discrepancy in the effective date of Amendment 39-4803. The effective date is March 12, 1984, instead of February 21, 1984, as was noted in the proposed rule. The FAA recognizes this error and has corrected the reference to the effective date appearing in paragraph (a) of the final rule.

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the change previously described. The FAA has determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

There are approximately 900 Boeing Model 737-100 and 737-200 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 300 airplanes of U.S. registry will be affected by this AD, that it will take approximately 1 work hour per airplane to accomplish the required actions, and that the average labor rate is $55 per work hour. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $16,500.

By revising the applicability of this rule, the number of affected airplanes is reduced by approximately 1,077 worldwide, including 595 of U.S. registry.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption "**ADDRESSES**."

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39-4803 (49 FR 5056, February 10, 1984), and by adding a new airworthiness directive (AD), amendment 39-8227, to read as follows:

92-09-02. Boeing: Amendment 39-8227. Docket 91-NM-218-AD. Supersedes AD 84-03-01, Amendment 39-4803.

Applicability: All Model 737-100 and 737-200 series airplanes, line number 001 through line number 900, certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent air leakage into the fuel feed lines within the wing tanks during fuel system suction feed operation at low fuel levels, accomplish the following:

(a) Prior to the accumulation of either 20,000 flight hours or 7 years of age, or within 500 flight hours, whichever occurs later after March 12, 1984 (the effective date of Amendment 39-4803), institute an inspection program in accordance with Boeing Service Bulletin 737-28-1047, Revision 3, dated November 19, 1987, or earlier FAA-approved revisions.

(b) An alternative method of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. The request shall be forwarded through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Seattle ACO.

(c) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

(d) The inspection program instituted shall be in accordance with Boeing Service Bulletin 737-28-1047, Revision 3, dated November 19, 1987. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington; or at the Office of the Federal Register, 1100 L Street NW., room 8401, Washington, DC.

(e) This amendment becomes effective on June 2, 1992.

Issued in Renton, Washington, on April 6, 1992.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 92-9864 Filed 4-27-92; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 39

[Docket No. 91-NM-283-AD; Amendment 39-8229; AD 92-09-04]

Airworthiness Directives; British Aerospace Viscount Model 744, 745D, and 810 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to British Aerospace Viscount Model 744, 745D, and 810 series airplanes, that requires visual inspection and rework of the nose and main landing gear retraction jack assemblies; removal of any obstructions, if necessary; and repair or replacement of damaged parts. This amendment is prompted by a reported failure of a nose landing gear to lower, while the normal extension landing gear system was being used. The actions specified by this AD are intended to prevent failure of one or more of the landing gears.

DATES: Effective June 2, 1992.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of June 2, 1992.

ADDRESSES: The service information referenced in this AD may be obtained from British Aerospace, PLC, Librarian for Service Bulletins, P.O. Box 17414, Dulles International Airport, Washington, DC 20041-0414.

This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue SW., Renton, Washington; or at the Office of the Federal Register, 1100 L Street NW., room 8401, Washington, DC.

FOR FURTHER INFORMATION CONTACT: William Schroeder, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington 98055-4056; telephone (206) 227-2148; fax (206) 227-1320.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations to include an airworthiness directive (AD) that is applicable to British Aerospace Viscount Model 744, 745D, and 810 series airplanes was published in the **Federal Register** on January 22, 1992 (57 FR 2486). That action proposed to require visual inspection and rework of the nose and main landing gear retraction jack assemblies; removal of any obstructions, if necessary; and repair or replacement of damaged parts.

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received on the proposal or the FAA's determination of the cost to the public. The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

The FAA estimates that 29 airplanes of U.S. registry will be affected by this AD, that it will take approximately 50 work hours per airplane to accomplish the required actions, and that the average labor rate is $55 per work hour. Required parts will be negligible in cost. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $79,750.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption "**ADDRESSES**."

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

92-09-04. British Aerospace. Amendment 39-8229. Docket 91-NM-283-AD.

Applicability: All Viscount Model 744, 745D, and 810 series airplanes, certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of one or more of the landing gears, accomplish the following:

(a) Within 500 hours time in-service or within 6 months after the effective date of this AD, whichever occurs first, accomplish

the following procedures in accordance with British Aerospace Viscount Alert Preliminary Technical Leaflet (PTL) 319 (for Model 744 and 745D series airplanes) or PTL 188 (for Model 810 series airplanes), both dated March 14, 1990, as applicable:

(1) Remove the nose and main landing gear retraction jacks. Remove the shuttle valve elbow connections, part numbers 70050–69 and 74450–117, and the shuttle, part number A5133–7, from the jacks, in accordance with the service bulletin.

(2) Ream the bore of each shuttle valve elbow connection, and chamfer the elbow bore aperture to 45 degrees. Remove the swarf and clean each shuttle valve elbow. If any residual obstructions or burrs are detected, prior to further flight, remove them in accordance with the service bulletin.

(3) Visually inspect the "hard chrome" plating of the shuttle for damage. If any damaged or binding shuttles are detected, prior to further flight, replace them with new parts, in accordance with the service bulletin.

(4) Visually inspect the bores in the retraction jack cylinder ends for obstructions. If any obstructions or damaged parts are detected, prior to further flight, remove or replace them in accordance with the service bulletin.

(5) Reassemble the shuttles and shuttle valve elbow connections to their respective retraction jacks. Immediately subsequent to installation and reassembly, perform bench checks on the retraction jack assemblies, in accordance with the Viscount Maintenance Manual, to ensure proper operation of the shuttle valves. If any malfunctioning parts are detected, prior to further flight, repair or replace them in accordance with the Maintenance Manual. Reinstall the retraction jacks on the airplane, bleed the hydraulic system and perform landing gear functioning checks in accordance with the Viscount Maintenance Manual. If any malfunctioning parts are detected, prior to further flight, replace or repair them in accordance with the Maintenance Manual.

(b) An alternative method of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate. The request shall be forwarded through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Standardization Branch, ANM–113.

(c) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

(d) The inspection and repairs shall be done in accordance with British Aerospace Viscount Alert Preliminary Technical Leaflet (PTL) 319 (for Model 744 and 745D series airplanes), dated March 14, 1990; or PTL 188 (for Model 810 series airplanes), dated March 14, 1990. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from British Aerospace, PLC, Librarian for Service Bulletins, P.O. Box 17414, Dulles International Airport, Washington, DC. 20041–0414. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington; or at the Office of the Federal Register, 1100 L Street NW., Room 8401, Washington, DC.

(e) This amendment becomes effective on June 2, 1992.

Issued in Renton, Washington, on April 7, 1992.

D. L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 92–9865 Filed 4–27–92; 8:45 am]

BILLING CODE 4910–13–M

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14 CFR Part 39

[Docket No. 91–NM–147–AD; Amendment 39–8224; AD 92–08–13]

Airworthiness Directives; British Aerospace Model ATP Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to certain British Aerospace Model ATP series airplanes, that currently requires a one-time inspection of the normal operating linkage to ensure that certain bolts are installed, and installation of these bolts, if necessary; and repetitive operational tests of the hydraulic landing gear change-over valve mechanism. If these systems do not operate properly, the airplane could experience a gear-up landing. This amendment adds a requirement for a modification of the undercarriage emergency release mechanism which, when installed, terminates the need for the currently required operational tests; and adds a requirement to inspect for proper installation of the swivel assembly in the landing gear normal selector mechanism. This amendment is prompted by the development of a modification which improves the existing design of the hydraulic landing gear change-over valve mechanism. The actions specified by this AD are intended to prevent a gear-up landing.

DATES: Effective June 2, 1992.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of June 2, 1992.

ADDRESSES: The service information referenced in this AD may be obtained from British Aerospace, PLC, Librarian for Service Bulletins, P.O. Box 17414, Dulles International Airport, Washington, DC 20041–0414. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue SW., Renton, Washington; or at the Office of the Federal Register, 1100 L Street NW., room 8401, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. William Schroeder, Aerospace Engineer, Standardization Branch, ANM–113, FAA, Northwest Mountain Region, Transport Airplane Directorate, 1601 Lind Ave. SW., Renton, Washington 98055–4056; telephone (206) 227–2148, fax (206) 227–1320.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations by superseding AD 90–21–11, Amendment 39–6806 (55 FR 47847, November 16, 1991), which is applicable to certain British Aerospace Model ATP series airplanes, was published as a supplemental notice of proposed rulemaking in the **Federal Register** on January 13, 1992 (57 FR 1230). The action proposed to add a requirement for a modification of the undercarriage emergency release mechanism which, when installed, terminates the need for the currently required operational tests; and add a requirement to inspect for proper installation of the swivel assembly in the landing gear normal selector mechanism.

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the single comment received.

The commenter supports the proposed rule.

Since issuance of the proposal, British Aerospace has issued Revision 3 of Service Bulletin ATP–32–30, dated May 20, 1991, which relates to the visual inspection of the swivel assembly in the teleflex cable. This revised service bulletin removes certain airplanes from its effectivity listing. The United Kingdom Civil Aviation Authority (CAA) has classified this revised service bulletin as mandatory. Accordingly, the FAA has revised paragraph (d) of the final rule to cite Revision 3 of that service bulletin as an additional source for service information, and to specify the serial numbers of the affected airplanes.

After careful review of the available data, including the comment noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the changes described previously. The FAA has determined that these changes will neither increase the economic burden on

any operator nor increase the scope of the AD.

The FAA estimates that 9 airplanes of U.S. registry will be affected by this AD, that it will take approximately 113 work hours per airplane to accomplish the required action, and that the average labor rate is $55 per work hour. Required parts will cost approximately $821 per airplane. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $63,324.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption "**ADDRESSES**."

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39-6806 (55 FR 47847, November 16, 1990), and by adding a new airworthiness directive (AD), amendment 39-8224, to read as follows:

92-08-13. British Aerospace: Amendment 39-8224. Docket 91-NM-147-AD. Supersedes AD 90-21-11, Amendment 39-6806.

Applicability: Model ATP series airplanes, serial numbers 2001 through 2037, certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent a gear-up landing, accomplish the following: (a) Within 24 hours after November 29, 1990 (the effective date of AD 90-21-11, Amendment 39-6806), and thereafter at intervals not to exceed 30 hours time-in-service, perform an operational test of the hydraulic landing gear change-over valve mechanism, in accordance with British Aerospace Alert Service Bulletin A-ATP-32-26, Revision 1, dated September 25, 1990. Any binding or stiffness must be corrected prior to further flight, in accordance with instructions in the manufacturer's maintenance manual.

(b) Within 60 days after the effective date of this AD, modify the undercarriage emergency release mechanism and perform the associated functional test on the up lock release mechanism, in accordance with the accomplishment instructions in British Aerospace Service Bulletin ATP-32-29, Revision 1, dated June 6, 1991.

(c) Modification of the undercarriage emergency release mechanism, in accordance with British Aerospace Service Bulletin ATP-32-29, Revision 1, dated June 6, 1991, constitutes terminating action for the repetitive operational tests required by paragraph (a) of this AD.

(d) For airplanes having serial numbers 2001 through 2019, 2023 through 2027, 2030, 2031, and 2033: Within 60 days after the effective date of this AD, accomplish the following in accordance with British Aerospace Service Bulletin ATP-32-30, Revision 2, dated April 22, 1991; or Revision 3, dated May 20, 1991:

(1) Perform a one-time visual inspection of the swivel assembly in the landing gear normal selector mechanism teleflex cable to ensure that the correct connector is fitted. If the correct connector is not fitted, prior to further flight, install a connector and replacement teleflex cable.

(2) Install clevis pins, at specified locations, in lieu of bolts in the normal selector mechanism.

(3) Perform functional tests of the landing gear normal selector mechanism.

(e) An alternative method of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate. The request shall be forwarded through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Standardization Branch.

(f) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

(g) The inspections, modifications, and repairs shall be done in accordance with British Aerospace Alert Service Bulletin A-ATP-32-26, Revision 1, dated September 25, 1990; British Aerospace Service Bulletin ATP-32-29, Revision 1, June 6, 1991; and British Aerospace Service Bulletin ATP-32-30, Revision 2, dated April 22, 1991, or Revision 3, dated May 20, 1991; which include the following list of effective pages:

Service bulletin	Page No.	Revision level	Date
A-ATP-32-26, Revision 1	1, 3	1	September 25, 1990.
	2	Original	September 21, 1990.
ATP-32-29, Revision 1	1, 3, 7, 13	1	June 6, 1991.
	2, 4, 5, 6, 9, 11, 14	Original	March 27, 1991.
	8, 10, 12	(Not used)	
ATP-32-30, Revision 2	1, 5, 11	2	April 22, 1991.
	2, 6	1	March 22, 1991.
	3, 4, 7, 9	Original	March 14, 1991.
	8, 10	(Not used)	
ATP-32-30, Revision 3	1	3	May 20, 1991.
	5, 11	2	April 22, 1991.
	2, 6	1	March 22, 1991.
	3, 4, 7, 9	Original	March 14, 1991.
	8, 10	(Not used)	

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from British Aerospace, PLC, Librarian for Service Bulletins, P.O. Box 17414, Dulles International Airport, Washington, DC. 20041-0414. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601

Lind Avenue SW., Renton, Washington; or at the Office of the Federal Register, 1100 L Street NW., room 8401, Washington, DC.

(h) This amendment becomes effective on June 2, 1992.

Issued in Renton, Washington, on April 1, 1992.

David G. Hmiel,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 92-9863 Filed 4-27-92; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 500

Foreign Assets Control Regulations

AGENCY: Office of Foreign Assets Control, Department of the Treasury.

ACTION: Final rule; amendments.

SUMMARY: As a further step in the process of normalization of relations between the United States and Vietnam, the Foreign Assets Control Regulations, 31 CFR part 500 (the "FACR"), are being amended to authorize telecommunications transactions involving Vietnam, provided that payments owed to Vietnam or its nationals are deposited into blocked interest-bearing accounts in domestic U.S. banks pending full lifting of the trade embargo. Reporting of the establishment of such accounts is also required.

EFFECTIVE DATE: April 23, 1992.

FOR FURTHER INFORMATION CONTACT: William B. Hoffman, Chief Counsel (tel.: 202/535-6020), or Steven I. Pinter, Chief of Licensing (tel.: 202/535-9449), Office of Foreign Assets Control, Department of the Treasury, Washington, DC 20220.

SUPPLEMENTARY INFORMATION: The Office of Foreign Assets Control ("FAC") is amending the FACR to add § 500.571, authorizing the telecommunications transactions of U.S. common carriers involving Vietnam. The general license for U.S. common carriers' transactions covers transactions of persons utilizing the services of such common carriers. Any payment owed to Vietnam or its nationals for such transactions must be made into a blocked interest-bearing account in a bank in the United States pending full lifting of the trade embargo. The establishment of each such blocked account must be reported to FAC within 30 days.

Because the FACR involve a foreign affairs function, Executive Order 12291 and the provisions of the Administrative Procedure Act, 5 U.S.C. 553, requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date, are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, does not apply.

This rule is being issued without prior notice and public procedure pursuant to the Administrative Procedure Act. For this reason, the collection of information contained in FACR § 500.571 has been reviewed and, pending receipt and evaluation of public reason, the collection of information contained in FACR § 500.571 has been reviewed and, pending receipt and evaluation of public comments, approved by the Office of Management and Budget under control number 1505-0096. Comments concerning the average annual burden and suggestions for reducing this burden should be directed to the Office of Management and Budget, Paperwork Reduction Project, Washington, DC 20503, with copies to the Office of Foreign Assets Control, U.S. Department of the Treasury, 1500 Pennsylvania Avenue, NW—Annex, Washington, DC 20220. Any such comments should be submitted not later than 60 days from publication.

The collection of information in this rule is contained in FACR § 500.571(b). This information is required by the Office of Foreign Assets Control for compliance, civil penalty, and enforcement purposes. This information will be used to determine the location of blocked Vietnamese assets in the United States, to determine whether persons subject to the requirements of the FACR are in compliance with applicable requirements, and to determine whether and to what extent civil penalty or other enforcement action is appropriate. The likely respondents are business organizations acting as common carriers for telecommunications transmissions.

Estimated total annual reporting and or recordkeeping burden: 5 hours.

The estimated annual burden per respondent/recordkeeper is expected to be one hour.

Estimated annual frequency of responses: one in the first year, none thereafter.

List of Subjects in 31 CFR Part 500

Banks, Blocking of assets, Reporting and recordkeeping requirements, Telecommunications, Vietnam.

For the reasons set forth in the preamble, 31 CFR part 500 is amended as follows:

PART 500—FOREIGN ASSETS CONTROL REGULATIONS

1. The authority citation for part 500 continues to read as follows:

Authority: 50 U.S.C. App. 5, as amended; E.O. 9193, 7 FR 5205, 3 CFR 1938-1943 Cum. Supp., p. 1174; E.O. 9989, 13 FR 4891, 3 CFR 1943-1948 Comp., p. 748.

Subpart E—Licenses, Authorizations and Statements of Licensing Policy

2. Section 500.571 is added to read as follows:

§ 500.571 Transactions related to telecommunications authorized.

(a) All transactions of U.S. common carriers incident to the receipt or transmission of telecommunications involving Vietnam are authorized, provided that any payment owed to Vietnam or any national thereof is paid into a blocked account in a domestic bank established exclusively for this purpose.

Note: Exports or reexports to Vietnam of goods and technical data, or of the direct products of technical data (regardless of U.S. content), not prohibited by this part may require authorization from the U.S. Department of Commerce pursuant to the Export Administration Regulations, 15 CFR parts 768-799.

(b) Within 30 days of the opening of each blocked account required pursuant to paragraph (a) of this section, the U.S. common carrier opening the account shall file a report with the Office of Foreign Assets Control, Blocked Assets Division, U.S. Department of the Treasury, 1500 Pennsylvania Avenue, NW.—Annex, Washington, DC 20220, stating

(1) The name, address, and telephone number of the common carrier,

(2) The name and address of the Vietnamese payee,

(3) The name, street address, and telephone number of the domestic bank holding the account, and

(4) The name and number of the blocked account.

Dated: April 17, 1992.

R. Richard Newcomb,

Director, Office of Foreign Assets Control.

Approved: April 21, 1992

Peter K. Nunez,

Assistant Secretary (Enforcement).

[FR Doc. 92-9787 Filed 4-23-92; 9:11 am]

BILLING CODE 4810-25-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 91-298; RM-7803]

Radio Broadcasting Services; Lake George, NY

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of William H. Walker, III, allots Channel 253A to Lake George, New York as the community's first local FM service. Channel 253A can be allotted to Lake George in compliance with the Commission's minimum distance separation requirements without the imposition of a site restriction, at coordinates North Latitude 43-25-42 and West Longitude 73-42-48. Canadian concurrence in the allotment as a specially negotiated channel allotment has been received since Lake George is located within 320 kilometers (200 miles) of the U.S.-Canadian border. With this action, this proceeding is terminated.

DATES: Effective June 5, 1992. The window period for filing applications will open on June 8, 1992, and close on July 8, 1992.

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 91-298, adopted April 9, 1992, and released April 22, 1992. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, Downtown Copy Center, (202) 452-1422, 1714 21st Street, NW., Washington, DC 20036.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under New York, is amended by adding Channel 253A, Lake George.

Federal Communications Commission.

Michael C. Ruger,

Acting Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 92-9889 Filed 4-27-92; 8:45 am]

BILLING CODE 6712-01-M

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47 CFR Part 73

[MM Docket No. 90-617; RM-7564]

Radio Broadcasting Services; Tahlequah, OK

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Demaree Communications, Inc., substitutes Channel 269C3 for Channel 269A at Tahlequah, Oklahoma, and modifies the license of Station KEOK(FM) to specify operation on the higher class channel. See 55 FR 52850, December 24, 1990. Channel 269C3 can be allotted to Tahlequah in compliance with the Commission's minimum distance separation requirements with a site restriction of 18.1 kilometers (11.3 miles) south to avoid short-spacings to the proposed reallotment of Channel 268C3 from Nowata to Collinsville, Oklahoma (MM Docket 91-255), to Station KISK, Channel 270C2, Lowell, Arkansas, as well as the Lowell reference coordinates, and to Station KBIX-FM, Channel 271A, Wagoner, Oklahoma, at coordinates North Latitude 35-46-16 and West Longitude 95-00-30. With this action, this proceeding is terminated.

EFFECTIVE DATE: June 5, 1992.

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 90-617, adopted April 9, 1992, and released April 22, 1992. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, Downtown Copy Center, (202) 452-1422, 1714 21st Street, NW., Washington, DC 20036.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Oklahoma, is amended by removing Channel 269A and adding Channel 269C3 at Tahlequah.

Federal Communications Commission.

Michael C. Ruger,

Acting Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 92-9892 Filed 4-27-92; 8:45 am]

BILLING CODE 6712-01-M

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47 CFR Part 73

[MM Docket No. 91-28; RM-7584]

Radio Broadcasting Services; Abilene and Colorado City, TX

AGENCY: Federal communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Sure Broadcasting, Inc., substitutes Channel 292C2 for Channel 292A at Abilene, Texas, and modifies the license of Station KHXS-FM to specify operation on the higher powered channel. To accommodate the allotment of Channel 292C2 to Abilene, the Commission also substitutes Channel 291A for Channel 292A at Colorado City, Texas, and modifies the license of Station KAUM-FM to specify the alternate Class A channel. See 56 FR 08975, March 4, 1991. Both channels can be allotted in compliance with the Commission's minimum distance separation requirements at the licensed sites of KHXS-FM and KAUM-FM, respectively. The coordinates for Channel 292C2 at Abilene are 32-28-34 and 99-42-22. The coordinates for Channel 291A at Colorado City are 32-23-15 and 100-53-33. Mexican concurrence has been obtained for the allotment of Channel 291A at Colorado City, Texas. With this action, this proceeding is terminated.

EFFECTIVE DATE: June 5, 1992.

FOR FURTHER INFORMATION CONTACT: Pamela Blumenthal, Mass Media Bureau, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 91-28, adopted April 13, 1992, and released April 22, 1992. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street, NW., Washington, DC. The complete text of

this decision may also be purchased from the Commission's copy contractor, Downtown Copy Center, (202) 452–1422, 1714 21st Street, NW., Washington, DC 20036.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Texas, is amended by removing Channel 292A and adding Channel 292C2 at Abilene, and by removing 292A and adding Channel 291A at Colorado City.

Federal Communications Commission.

Michael C. Ruger,

Acting Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 92–9890 Filed 4–27–92; 8:45 am]

BILLING CODE 6712–01–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 216

[Docket No. 920117–2017]

Taking and Importing of Marine Mammals

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of embargo.

SUMMARY: The Assistant Administrator for Fisheries, NOAA (Assistant Administrator), announces that yellowfin tuna and yellowfin tuna products harvested by purse seine vessels from the Republic of Colombia operating in the eastern tropical Pacific Ocean (ETP) are prohibited from entry into the United States until further notice.

DATES: This finding is effective April 27, 1992, and remains in effect until further notice.

FOR FURTHER INFORMATION CONTACT: E.C. Fullerton, Regional Director, Southwest Region, National Marine Fisheries Service, NOAA, 501 W. Ocean Boulevard, suite 4200, Long Beach, CA 90802–4213, Phone (310) 980–4001.

SUPPLEMENTARY INFORMATION: The Marine Mammal Protection Act (MMPA) (16 U.S.C. 1361 et seq.) requires a ban on the importation of commercial fish or products from fish that have been caught with commercial fishing technology which results in the incidental kill or serious injury of ocean mammals in excess of United States standards. In the case of yellowfin tuna from the ETP, the MMPA requires the ban unless nations have met standards comparable to those of the United States. The MMPA's ban also applies to intermediary nations from which yellowfin tuna or tuna products will be exported to the United States, unless they have acted to ban "such products" from countries whose yellowfin tuna is embargoed by the United States. NMFS regulations (50 CFR 216.24(e)(5)) ban the importation of tuna or tuna products specified by U.S. Harmonized Tariff Schedule Item Numbers from harvesting nations that have not met the comparability standards of the MMPA, and from intermediary nations that have not acted to ban tuna and tuna products from nations embargoed by the United States.

On October 8, 1991, NMFS published an interim final rule (56 FR 50672) that, among other things, established a new fishing season and a schedule for request of findings. The new fishing season was established as the period October 1 through the following September 30. An annual report summarizing all fishing trips completed during this 12-month period must be submitted to the Assistant Administrator by December 1, and a finding will be made by December 31. Additional information on the criteria for making findings can be found in the cited rule and need not be repeated here.

NMFS has reviewed the marine mammal regulatory program established by the Republic of Colombia, and finds that Colombia has enacted legislation to establish a marine mammal regulatory program similar to that of the United States. NMFS has also reviewed the report summarizing the activities of that nation's tuna purse seine fleet operating in the ETP during the 1991 fishing season (October 1, 1990 through September 30, 1991) and finds for the 1991 fishing season, based on Inter-American Tropical Tuna Commission observer records, that there were no observed dolphin mortalities. Therefore, the requirement that the nation's incidental kill-per-set factor is no more than 1.25 times that of the United States and the percent of the total kill for eastern spinner and coastal spotted dolphin was no more than 15.0 percent and 2.0 percent, respectively, is satisfied (50 CFR 216.24(e)(5)(v) (F) and (G)). However, the Assistant Administrator also finds that the level of observer coverage during the period was 40 percent. A proposed determination to accept an alternative international observer program, published October 18, 1990 (55 FR 42235), and effective on December 17, 1990, requires a minimum 75 percent level of observer coverage in 1991.

Therefore, in adherence with the regulations and court orders, the Assistant Administrator announces that the importation of yellowfin tuna or products derived from yellowfin tuna harvested with purse seines in the ETP by the Republic of Colombia is prohibited until further notice. Under 50 CFR 216.24(e)(5)(xiv), all intermediary nations which export yellowfin tuna and tuna products to the United States and also import yellowfin tuna and tuna products from the Republic of Colombia must certify to the Assistant Administrator that they have acted within 60 days of the U.S. ban to prohibit imports of yellowfin tuna and tuna products harvested by purse seine in the ETP from Colombia. Yellowfin tuna and tuna products harvested in the ETP by purse seine from intermediary nations which fail to provide such certification within 90 days of the effective date of this notice will not be allowed to enter the United States.

Dated: April 15, 1992.

Michael F. Tillman,

Deputy Assistant Administrator for Fisheries.

[FR Doc. 92–9798 Filed 4–27–92; 8:45 am]

BILLING CODE 3510–22–M

Proposed Rules

Federal Register
Vol. 57, No. 82
Tuesday, April 28, 1992

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Farmers Home Administration

7 CFR Part 1944

Section 502 Rural Housing Loan Policies, Procedures, and Authorizations

AGENCY: Farmers Home Administration, USDA.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Farmers Home Administration (FmHA) is considering changes to the Single Family Housing program. This program was authorized under section 502 of the Housing Act. The intended effect of this action is to make the program more user-friendly. FmHA invites proposals from the public on (1) using the HUD "CAP" in defining modest housing; (2) using ratios in lieu of a fmaily budget; (3) revising the method for interest credit calculation and (4) revising the method for selection and processing of applications.

DATES: This advance notice of proposed rulemaking is subject to a comment period ending May 28, 1992.

ADDRESSES: Submit written comments, in duplicate, to the Office of the Chief, Regulations, Analysis and Control Branch, Farmers Home Administration, USDA, room 6348, South Agriculture Building, 14th and Independence Avenue, SW., Washington, DC 20250. All written comments made pursuant to this notice will be available for public inspection during regular working hours at the above address.

FOR FURTHER INFORMATION CONTACT: Betty Obst, Senior Loan Officer, Single Family Housing Processing Division, USDA, room 5344–S, Washington, DC, telephone (202) 690–1488.

SUPPLEMENTARY INFORMATION: FmHA is considering making regulation revisions to the Single Family Housing Program which will, Eliminate specific characteristics, amenities, and restrictions relative to "modest housing" and rely on the dollar "CAP" established by HUD; move to an income ratio basis, which is used to determine the applicant's repayment ability in lieu of Form FmHA 1944–3, (Budget and/or Financial Statement); revise the method for calculation for interest credit assistance to provide that assistance will be provided based on a floor rate corresponding to the applicant/borrower's income range. Applicants/borrowers receiving a loan within a high cost area will be granted an additional one percent assistance with a floor rate limited to one percent; and revise the application processing section to eliminate the current method of selection to provide for a separate reserve of loan funds held by the State Director for priority applications which will be processed immediately and will not compete for the pool of funds used for other applicants. Priority applications will include hardship cases as determined by the State Director on a case-by-case basis; refinancing of certain FmHA and non-FmHA debts; subsequent loans for essential improvements or repairs, in connection with credit sales, and in connection with a transfer in order to avoid a foreclosure if it is to the Government's interests; and mutual self-help housing loans. Remaining applicants will be considered for eligibility in date order and selected for processing on a quarterly basis based on 175 percent of the anticipated quarterly allotment. A Certificate of Eligibility, valid for 90 days, will be issued to eligible RH applicants who have been selected for processing.

Written proposals will be received for a period of 30 days from the date of this publication.

This program is listed in the catalog of Federal Domestic Assistance under 10.410, Low-Income Housing Loans. This program is excluded from the scope of Executive Order 12372 which requires intergovernmental consultation with State and local officials.

Dated March 18, 1992.

La Verne Ausman,

Administrator, Farmers Home Administration.

[FR Doc. 92–9784 Filed 4–27–92; 8:45 am]

BILLING CODE 3410–07–M

7 CFR Part 1980

Rural Housing Loans

AGENCY: Farmers Home Administration, USDA.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Farmers Home Administration (FmHA) is considering revisions in its Guaranteed Rural Housing Program. The intended effect of this action is to make the program more user-friendly, improve the acceptability of the program to lenders and the secondary market for mortgage loans, to remove FmHA internal administrative procedures from the **Federal Register**, and to make adjustments and needed changes as a result of the Agency's experience in the first year of implementation of the program.

DATES: This advance notice of proposed rulemaking is subject to a comment period ending May 28, 1992.

ADDRESSES: Submit written comments in duplicate to the Office of the Chief, Regulations, Analysis and Control Branch, Farmers Home Administration, U.S. Department of Agriculture, room 6348, South Agriculture Building, 14th and Independence, SW., Washington, DC 20250. All written comments will be available for public inspection at the above address.

FOR FURTHER INFORMATION CONTACT: Michael S. Feinberg, Senior Loan Specialist, at Farmers Home Administration, USDA, room 5334–S, South Agriculture Building, 14th and Independence SW., Washington, DC 20250, Telephone (202) 720–1474.

SUPPLEMENTARY INFORMATION: On April 17, 1991 (56 FR 15748), FmHA published a final rule implementing the Guaranteed Rural Housing program. The program was authorized under the Cranston-Gonzalez National Affordable Housing Act.

FmHA implemented the program in 20 pilot states on May 17, 1991. Implementation of the program on a pilot basis enabled FmHA to identify areas where the program may need to be "fine-tuned" to broaden its acceptability.

FmHA is considering making revisions to the loan servicing and liquidation requirements to make loan servicing requirements more like loan servicing

for Federal Housing Administration loans to the extent practical given FmHA's existing computer system. The Agency would like to make its program requirements so that they fit into the existing servicing systems used in the mortgage loan industry.

FmHA is considering removal of the requirement for the use of a cost handbook in determining replacement cost value. Replacement cost would no longer be required for existing dwellings; those dwellings which are more than a year old. FmHA is also considering removal of the requirement for attachment for all supporting calculations.

The Agency is considering adding a provision for the appraiser to complete an environmental checklist. The intent of this is to help FmHA determine the need for further investigation of the site for environmental reasons. FmHA is particularly interested in comments from persons knowledgeable in the appraisal industry as to how this might impact the cost and timing of the appraisal. The proposed environmental checklist is fairly similar to the "Appraiser Checklist" used by the Department of Housing and Urban Development. Interested parties may obtain further information by contacting FmHA at the address above.

Interested parties are invited to participate in this advance notice of proposed rulemaking by submitting such written data, views, arguments, or proposals as they may desire. Comments relative to the issues noted above as well as any other areas of the current RH guaranteed loan program which they feel could be improved to make the program more consistent with the existing mortgage industry are invited. Comments are specifically solicited on the reduction or revision of forms or other methods of streamiling, to include the elimination of processing steps seen as overly burdensome or unnecessary, which will improve the acceptability of the program to lenders and the secondary market for mortgage loans. Comments and proposals should include illustrations and/or references to forms and procedures utilized in other program areas in the industry.

Written proposals will be received for a period of 30 days from the date of this publication.

This program is listed in the catalog of Federal Domestic Assistance under 10.429, Guaranteed Rural Housing Loans—Demonstration Program.

For the reason set forth in the final rule related notice to 7 CFR part 3015, subpart V, 48 FR 29115, June 24, 1983; this program/activity is excluded from the scope of Executive Order 12372 which requires intergovernmental consultation with State and local officials.

Dated: March 18, 1992.

La Verne Ausman,

Administrator, Farmers Home Administration.

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 110

RIN 3150-AD36

Import and Export of Radioactive Wastes

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its licensing requirements regarding the import and export of radioactive wastes. The proposed amendments reflect the decision of the General Conference of the International Atomic Energy Agency in September 1990 approving a voluntary Code of Practice to guide Nation States in the development and harmonization of policies and laws on the international transboundary movement of radioactive waste. The proposed amendments are intended to conform U.S. policies with these international recommendations.

DATES: Comment period expires July 13, 1992. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only of comments received on or before this date.

ADDRESSES: Mail written comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

Deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m. Federal workdays.

Copies of comments received may be examined at: The NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC, between 7:30 a.m. and 4:15 p.m. Federal workdays.

FOR FURTHER INFORMATION CONTACT: Ronald Hauber, Office of International Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone 301/504-2344.

SUPPLEMENTARY INFORMATION:

Introduction and Purpose

The Nuclear Regulatory Commission (NRC) issued an advance notice of proposed rulemaking (ANPR) on February 7, 1990 (55 FR 4181) to solicit public comments on possible options with respect to imports and exports of radioactive waste. The ANPR was issued in the context of ongoing Commission interactions with the U.S. Department of State and other Federal agencies regarding the Commission's interest in helping to develop a broad U.S. policy in regard to these imports and exports.

The ANPR referred to the work of the International Atomic Energy Agency (IAEA) voluntary code of practice on transboundary shipments of radioactive waste. This effort was supported by the U.S. Government. A final document was approved by the IAEA General Conference in Vienna, Austria in September 1990. A basic principle of the code of practice is that international exports of radioactive waste should take place with the prior notification and consent of the sending, receiving, and transit countries.

At present, the NRC's import and export licensing requirements are concerned primarily with nuclear proliferation controls. Radioactive materials of little or no significance with respect to national security are currently allowed to enter or leave the U.S. under general import and export licenses. Thus, currently, imports or exports of nuclear waste may take place without issuance of a specific license by the NRC and without the NRS's knowledge. By amending part 110, in the manner discussed below, to require specific licensing of such imports or exports, the NRC will be strengthening its controls over radioactive waste entering or leaving the United States.

The ANPR reflected concerns that international transfers of radioactive wastes to and from the U.S., in particular low-level radioactive wastes (LLW), should be subject to more control. The Commission sought comments from the public, industry, and other government agencies on four regulatory options and several related issues. The ANPR stated the NRC's preliminary judgment that the best approach would be to develop a policy that provides greater control and accountability over the export and import of radioactive waste. The ANPR also stated that this policy could lead to an amendment to the NRC's existing regulations in part 110 to require advance notification and/or consent for radioactive waste exports or imports.

Thirty letters of comments were received in response to the ANPR. The comments addressed various aspects of the four regulatory options and thirteen associated questions. A discussion of the general comments of the low-level waste compacts, and the public comments on the four options and thirteen questions, is given below:

General Comments by Low-Level Waste Compacts

The Southeast Compact Commission offered four general comments, as follows:

1. As a matter of policy, the Commission should recognize that most low-level radioactive waste compacts have adopted a policy controlling the import and export of low-level waste to and from their respective regions. Authority to enforce restrictions has been granted by the Congress in its approval of compact legislation. The ANPR gives little recognition of this fact.

NRC Response: The authority of the low-level waste compacts (Compacts) and States is recognized in the proposed rule. The NRC would coordinate its import licensing actions closely with interested Compacts and States. An NRC import license would not be issued in a particular case unless there were a disposal facility willing and able to receive it, including having the necessary authorization from State-level officials. Neither Compacts nor States have any authority over exports of low-level radioactive waste from the United States although they may have authority to bar such waste from leaving their respective regions or jurisdictions.

2. The NRC must provide specific notice of any approved, impending imports and exports to all low-level Compacts which may be impacted. The portal State should also be notified of such shipments.

NRC Response: The NRC will inform interested Compacts and States prior to issuing a license to authorize the import or export of radioactive waste. However, the proposed rule does not place reporting requirements on shippers with regard to notifying the NRC of the actual route and schedule of each authorized import or export of radioactive waste. The Compacts and States might be able to place their own reporting requirements on shippers. In the case of imports, such reporting requirements might be imposed as a condition of authorizing a disposal facility to receive the shipper's material.

3. It is believed that Congress did not contemplate the foreign importation or exportation of waste that would violate a Compact's expressed desires to deny such domestic importation from or exportation to another region of this country.

NRC Response: The NRC believes the proposed rule complies with Congressional requirements and respects the role and authority of the Compacts and States with respect to low-level radioactive waste. It does not preempt the authority of the Compacts or States to control the movement of low-level waste into or out of a regional or State facility.

4. Because the imported and exported material may have low economic value and might be abandoned in the event of an accident, appropriate financial assurance must be obtained for these wastes.

NRC Response: The proposed rule does not establish any special requirements for financial assurances as a condition for the NRC issuing an import or export license. The NRC staff believes it would be difficult to justify requiring financial assurances for waste shipments when assurances are not required for other shipments of radioactive materials which have low economic value. However, the Commission's decision criteria for licensing imports or exports of radioactive waste include a determination of whether or not the proposed import or export would minimize public health, safety, and environmental impacts in the U.S. and the global commons. This criterion could lead to an examination of the shipper's qualifications and past performance in light of the potential risks to the public and the environment. Moreover, the NRC will consult with State officials and the Department of State will consult with foreign officials to identify concerns in particular cases and allow those officials or others to require special financial assurances, outside the specific framework of the NRC's import-export regulations.

The Central Midwest Interstate Low-Level Radioactive Waste Commission, in addition to several specific comments on the options, noted:

1. Policies adopted by the NRC must allow the Compact commissions to exercise their authority over low-level waste disposed of in their regions.

NRC Response: The NRC agrees, as discussed above and as reflected in the proposed rule.

2. The public must be confident that their health and safety is being protected by an agency (NRC) that places the burden of proof on industry to demonstrate that imports or exports will not pose a threat to them.

NRC Response: The NRC believes its proposed rule should be helpful in assuring public confidence in this regard.

3. The NRC's regulations should contain explicit statements acknowledging that compliance with federal regulations is necessary, but not sufficient. The NRC should explicitly recognize the authority granted to the Compacts by the Low-Level Radioactive Waste Policy Amendments Act to control "imports and exports" of waste across their regional boundaries.

NRC Response: The introduction to the proposed rule states that the NRC's import/export licensing authority only controls the entry or exit of the radioactive waste into or out of the jurisdiction of the United States. It does not authorize possession of the materials nor does it in anyway assure access to a disposal facility or preempt the authority of the Compacts or States in respect to the movement of radioactive waste into or out of a region or State.

The Pennsylvania Department of Environmental Resources, with particular reference to the Appalachian States Compact, observed:

1. No low-level radioactive waste may be imported or exported into the Compact region for disposal at the regional facility without authorization as provided by law.

NRC Response: The proposed rule does not preempt the authority of the Compacts or States to control the movement of low-level waste into or out of a region or State.

2. When the Appalachian States disposal facility begins operation in Pennsylvania, the import or export of any low-level radioactive waste for disposal purposes is effectively banned. Any exception would have to be approved by the Compact commission and/or the legislature of the host State.

NRC Response: The proposed rule does not preempt the authority of the Compacts or States to control the movement of low-level waste into or out of a region or State.

Public Comments on the Four Options and Thirteen Questions

Option 1: Maintain the status quo.

Several commenters preferred Option 1. They said a need for change is not evident; any proposed rulemaking would be based on conjecture about potential future problems; the Compacts are able to restrict transfers in and out of their regions; and if there is any inconsistency in the regulation of domestic- and foreign-origin waste disposal the regulations governing domestic possession and use could be modified.

Others opposed Option 1 because this option does not provide adequate control, is not appropriate in view of international concern about extraterritorial waste dumping, and does not keep the NRC informed about waste exports and imports.

The NRC carefully considered the comment that regional Compact restrictions on waste moving in or out of the Compact obviated the need for additional NRC import and export controls on radioactive wastes. However, the NRC concluded that neither these restrictions, nor conditions placed on materials licenses by the NRC or the Agreement States, effectively control exports or imports of wastes under the general licenses in Part 110.

Overall, Option 1 does not ensure that the Commission would be informed of radioactive waste exports from the U.S. or of imports into this country and does not provide the degree of control and international consultation recommended by the IAEA Code of Practice.

Option 2: Notification of the NRC.

One commenter favored this option, if any change is needed. Two supported this option in combination with Options 3 (specific licensing) and 4 (international agreements).

Several commenters opposed this option; some because it would be too restrictive or burdensome; others because it would be ineffective or would offer an insufficient degree of control.

The Department of State commented that this option, by itself, is not appropriate in view of international concerns. The NRC believes that a notification-only option is insufficient in regard to assuring adequate government control to allay worldwide concerns about waste dumping and conform with the IAEA Code of Practice.

Option 3: Require specific licenses to import or export radioactive waste.

One commenter opposed Option 3. This commenter believed that it is unnecessary to control waste imports to the U.S. because of the import provisions of the Low-Level Radioactive Waste Policy Amendments Act and current requirements for obtaining site use permtis and for identifying waste generators at the current disposal sites. The commenter said acknowledgement of the receiving country may be useful to prevent an inappropriate export of waste but that this is possible without licensing. One commenter observed that Option 3 demands trust in the NRC to administer the program and that the public may not trust the NRC to assure that foreign "BRC" (below regulatory concern) wastes will not end up in municipal landfills or incinerators in the U.S.

Several commenters supported Option 3 either alone or combined with Option 4. Option 3 was generally recognized as ensuring effective control, yet providing some flexibility. One commenter supported Option 3 because the licensing process allows possible public participation which would be unavailable under Option 4. Another commenter said Option 3 would provide for host State control over waste disposal and appropriate review by the affected Compact commission.

The Department of State preferred Option 3, noting that it should ensure, through advance notice of proposed waste imports and exports, the opportunity to control these transactions based on the consent of the importing country. The NRC also favors Option 3. The NRC would eliminate the use of existing general licenses under part 110 for radioactive waste exports and imports except to return sealed sources and other materials to the country of origin to a consignee who is authorized to possess them.

Option 4: Ban imports and exports of radioactive waste except under international disposal agreements.

Comments were about equally divided on this option. Supporters generally favored combining it with Option 3 (specific licensing) to achieve adequate control over imports and exports. One commenter suggested using this combination to ensure that exported wastes do not reappear as contaminated scrap. Those opposing Option 4 thought this option could be inflexible and difficult to implement. One commenter said that there may be little opportunity for public participation and litigation in connection with international agreements negotiated by the Department of State.

The Department of State said there had been no documentation of a waste dumping problem sufficient to justify expending substantial resources developing and negotiating a potentially complex set of agreements with prospective importing countries. The NRC agrees with the Department of State that it is not necessary to require formal agreements with other countries in order to determine the receiving government's acceptance of a proposed shipment of radioactive waste. This can be done by the Department of State in consultation with the receiving government prior to the NRC's issuance of an export license.

Question 1: What are the economic advantages and disadvantages to the import and export of radioactive wastes?

The responses to this question emphasized the current uncertainties about the number, location, and capacity of domestic disposal sites now being planned, as well as uncertainties in the future domestic demand for storage at those sites, cost factors, etc. The NRC agrees that there are a large number of unknowns and that requiring specific NRC licenses for radioactive waste imports and exports will help ensure that all relevant considerations can be taken into account at the time each licensing decision is made.

Question 2: Are there policy, health and safety, or economic disadvantages to denying import or export of certain radioactive wastes, e.g., interference with ongoing U.S. international trade in sealed sources and gauges used in medical or other applications?

Three public interest groups expressed the view that the NRC should not be concerned with economic disadvantages but should limit its concern to public health and safety and the environment. Several commenters (source suppliers and States) recognized an economic disadvantage for U.S. source suppliers if they are not allowed to take back used sources because the sale of a source is often conditioned on later return of the source for disposal. One commenter said that if return of used sources was prohibited by import restrictions, U.S. suppliers would set up foreign companies with a possible negative economic impact on the U.S. One State official commented that on a case-by-case basis there may be health and safety advantages or disadvantages to denying import or export of certain wastes. Others noted that medical sources or instruments, although perhaps a small part of the possible volume of exports and imports of radioactive waste, produced benefits which may offset the environmental cost of disposal. Another commenter believes that waste imports and exports should be minimized, with approvals granted only when necessary to protect the public health and safety and the environment.

The NRC believes that the return of used or depleted sealed sources, gauges, and similar items to the U.S. or to another original exporting country for reconditioning, recycling or disposal may be appropriate for a number of reasons, but especially to help ensure that such materials are handled responsibly and not left in dispersed and perhaps unregulated locations around the world.

Question 3: Would it be in the interest of U.S. foreign policy to assist certain countries with the disposal of their radioactive wastes?

Commenters acknowledged that foreign governments might appreciate any assistance the U.S. could give them on waste disposal, but that the U.S. should provide help on policies, regulations, and institutions for handling wastes, rather than agree to import their waste when we have not solved our own problems in this area.

The NRC believes that specific licensing of low-level radioactive waste (LLW) exports and imports, as contemplated in the proposed rule, will allow important foreign policy considerations to enter into the decision process, but that these considerations would not supersede primary U.S. domestic interests.

Question 4: Does the U.S. have an adequate mechanism to dispose of imported radioactive wastes without adversely impacting the disposal of domestically generated wastes?

Commenters noted that the U.S. has not yet demonstrated its ability to handle disposal of domestic waste under the siting process defined in the Low-Level Radioactive Waste Policy Amendments Act (LLRWPAA) of 1985. The commenters identified other uncertainties which made the impact of any foreign waste imports difficult to judge. One commenter noted that the intent of Congress under the LLRWPAA was to make the States responsible for their own wastes, not imported wastes. An operator of a disposal site commented that current requirements for site use permits and identification of generators ensure appropriate approvals by State regulatory agencies before wastes are imported for disposal and obviate the need for additional regulation of imports of waste into the U.S.

The NRC believes the answer to this question depends largely on the success of the LLRWPAA's siting process.

Question 5: Would imported radioactive wastes be similar to radioactive wastes generated in the U.S. and therefore not likely to result in new radiological and/or environmental problems?

Commenters were not sure of the nature of foreign waste, but some assumed it would be similar to U.S. waste. There was some concern that imported waste could differ and that control at the generator's facilities could be a problem. There was a view that an accountable agency providing third party inspections would be essential to ensure that foreign waste streams meet Federal and importing States' specific requirements.

The NRC agrees that a verification system would need to be in place to assure that imported wastes meet U.S. standards. Existing mechanisms could be used for this purpose.

Question 6: What are the views of operators of disposal facilities and State and local governments on the import of radioactive wastes?

The one site operator who responded to the question said the NRC had implied in the ANPR that a Compact site might be required to accept foreign waste unless a change is made in part 110. However, the operator noted that a Compact has the authority to deny access to any out-of-Compact generator, including foreign ones. Several State agencies said that imports should only take place under exceptional circumstances on a case-by-case basis when the environment and public health and safety are at risk.

State agencies, as well as the one local government official that responded to the question, expected that local governments would oppose imports, probably at least into the 21st Century. A regional Compact official stressed his view that Congress did not contemplate foreign imports and exports that would violate a Compact's expressed desires to deny domestic (inter-Compact) imports and exports. The official said that if any foreign imports or exports are approved, specific notice should be given to portal States and impacted Compacts, and financial assurances should be provided to cover accidents.

The NRC notes that neither this question nor any others in the ANPR were intended to show a predisposition to approve radioactive waste imports without regard to the acceptability of the proposed actions to interested States and Compacts. Also, the NRC emphasizes that its exercise of import and export control at the borders of the U.S. is independent of the control which the States and Compacts may possess over radioactive waste while it is in the U.S.

Question 7: Are national authorities in countries that might receive U.S.-exported wastes technically competent to dispose of these wastes and would they agree to its receipt?

Commenters recognized that countries differ widely in their technical competencies, with the major nuclear power-producing countries generally most advanced in waste handling technology. Some commenters said that if any countries are willing to receive U.S.-exported waste, the U.S. should ensure that these host countries have the technical and other competence necessary to handle the waste safely.

The NRC believes that any waste exports should be confined to countries which are willing to receive them and which have regulated waste disposal programs. The NRC knows of no countries currently willing to receive our wastes.

Question 8: Should the capability of a recipient country to manage and dispose of radioactive wastes safely be considered in any NRC export license review process, recognizing that NRC authority to deny a license on these grounds is questionable?

Most commenters favored consideration of the capability of the receiving country in order to protect populations and the environment from incompetent disposal activities, as well as for moral and economic reasons. One commenter stated that criteria should be developed and implemented to evaluate host country capabilities prior to licensing. Another suggested that international agreements be used to provide the legal authority for the NRC to consider the capability of the host country.

Among the licensing criteria which the NRC would apply to its review of proposed radioactive waste exports are two which are relevant to this question. The NRC would consider the extent to which the proposed export would minimize public health, safety, and environmental impacts in the U.S. and the global commons. The NRC would also consider whether or not the proposed export would be acceptable to the competent regulatory authority of the receiving country. The NRC does not contemplate any circumstances in which a license would be issued to export to a country without a regulated waste disposal program or to a country whose government is opposed to receiving the waste.

Question 9: Would the export of some or all categories of radioactive wastes help solve a significant problem in the U.S., such as limited available disposal capacity?

Commenters noted that export of radioactive waste might be seen as the solution to the problem of developing low-level waste disposal sites but, unless all U.S. wastes were to be exported, would drive up the cost of disposing of whatever low-level wastes remained for domestic disposal and thus would serve as an economic disincentive to development of new sites.

The NRC agrees that exporting waste may cause more problems than it solves and should only be licensed when a case is made in support of a particular proposal. Any shortage of U.S. disposal capacity would only be a short-term condition.

Question 10: The NRC cannot currently regulate Naturally Occurring

or Accelerator Produced Material. Are provisions needed for the import and export of these wastes, assuming the NRC were given statutory authority over these materials?

Commenters seemed to favor the NRC regulation (and LLW Compact disposal) of accelerator-produced wastes, but were less sure with respect to naturally-occurring wastes such as pipe scale and gypsum piles which might be best left unregulated by the NRC.

As indicated in the question itself, the scope of the NRC's authority is not decided by the NRC but is set by law. At present the NRC does not have regulatory authority over naturally occurring and accelerator-produced wastes.

Question 11: Are there other means to broaden the Commission's information base with regard to transactions of exports and imports of radioactive wastes, exclusive of requiring specific licenses or otherwise revising the NRC's existing regulations?

Commenters suggested that international agencies or diplomatic channels might provide transaction information or that the U.S. might conduct a survey of radioactive materials brokers, processors, and site operators in the U.S. Another suggestion was to require licensees to keep records for NRC review or to submit an annual report to the NRC on waste types, volumes, activities, and destinations.

The NRC appreciates the suggestions which were offered, but has opted for specific licensing as a means of increasing its cognizance and control with respect to radioactive waste imports and exports.

Question 12: What import/export controls and licensing criteria may be necessary for various categories of radioactive waste and under what circumstances should imports and exports be considered wastes?

This broad question produced extensive comments covering the whole spectrum of options. One public interest group opposed NRC controls and asked for a complete ban. Others urged minimization of radioactive waste imports and exports, supporting only those actions necessary to protect health and safety and the environment, but also allowing the return of sealed radiation sources to the manufacturer. One said the NRC should use specific licensing to control international trade in sealed sources and to ban the import of low-level waste generated by the nuclear fuel cycle. Another said the NRC should ban specific waste forms, allowing the return of spent sealed sources to the manufacturer but not directly to a disposal facility except when such a prohibition of this type would have a detrimental impact on the environment or public health and safety in the U.S. or abroad and when no other safe alternative exists.

Another commenter stated that the NRC's system of regulations, license conditions, and definitions should be used for the rest of the world and that the Resource Conservation and Recovery Act requirements could be used to ensure proper identification and characterization of mixed wastes. Others said that wastes should be accompanied by specific manifests and there should be legal certifications by receivers that they have the authority to accept the waste shipments and wish to accept them. Another said it could be useful for the receiving country to acknowledge the acceptability of the waste import before the export is authorized.

The Department of State recommended that it obtain written consent of the recipient country and ask the country to confirm receipt of the import when it occurs. The Department of State also said that the NRC's rulemaking should exclude:

(a) Waste imports and exports in support of U.S. Government waste research and development testing programs under international arrangements,

(b) Military shipments that the U.S. Government makes to itself, between foreign and domestic bases, pursuant to arrangements with another country, and

(c) Shipments made pursuant to other arrangements concluded between the U.S. and the other governments providing entry and transit through the other nation (e.g., the 1944 Convention on International Civil Aviation).

The NRC accepted several of the suggestions in developing the definitions, exceptions, procedures, and licensing criteria presented in this proposed rulemaking. Regarding the Department of State/Executive Branch recommendations:

(a) International research and development shipments would be excluded from any new requirements because the shipped waste is being sent for research purposes, not just for disposal;

(b) Military and other U.S. Government shipments involving the return of radioactive waste to the U.S. (to an authorized Federal facility) would be excluded; and

(c) Nothing in the proposed new requirements would effect entry and transit rights under international shipping conventions.

Question 13: What assurances can be made that the Below Regulatory Concern (BRC) policies of various countries are consistent so that radioactive wastes declared to be BRC in the exporting country are indeed BRC wastes in the recipient country?

Several commenters expressed objections to Below Regulatory Concern as a regulatory concept or policy. One said that the problem is best solved by minimizing import and export of radioactive wastes and addressing BRC by specific international agreement when necessary and prior to import or export activity. Another said that BRC policy for imports should be the same as U.S. domestic BRC policy. Yet another commenter observed that it is not clear why a generator of BRC wastes would wish to export them.

The NRC has made no special provision for BRC material in its proposed rule. Future BRC determinations by the Commission may or may not be applied to waste imports and exports under part 110, depending on how they are formulated and on Commission policy at that time.

Overview of the Proposed Rule

The proposed rule would require a person to file an application for a specific license to export or import radioactive waste. The applicant would be required to include information on the volume of wastes, the waste classification, its chemical and physical characteristics, and whether a disposal site operator had agreed to accept the waste. A notice of receipt of each application would be published in the **Federal Register**. The views of the Executive Branch would be requested from the Department of State on proposed exports, and time would be available for NRC consultations with other Federal agencies and interested States and low-level waste Compacts on proposed imports. The NRC would have exclusive jurisdiction for granting or denying all licenses.

The NRC review would be governed by the following criteria: Would a proposed export or import minimize public health, safety, and environmental impacts in the United States and the global commons? Would a proposed export be acceptable to the competent regulatory authority of the receiving country? And would a proposed export be inimical to the common defense and security interests of the United States?

Following its review, the NRC would recommend to the Commission approval or denial of the license. If the Commission approved the issuance of an import or export license, such license would only authorize the waste material to enter or exit the jurisdiction of the

United States. The NRC import or export license alone would not authorize possession of the material and would not guarantee access to a disposal site in the U.S. Or another country. In the case of waste imports, the NRC would consult with interested States and low-level waste Compacts prior to issuing an import license and generally would not grant a license unless it was clear that the waste would be accepted by a disposal site and its host State and Compact.

Environmental Impact: Categorical Exclusion

The NRC has determined that pursuant to §§ 51.10 and 51.22(c)(1) of this chapter, these proposed amendments to part 110 require neither an environmental impact statement nor an environmental assessment.

Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). This rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements.

The public reporting burden for this collection of information is estimated to average 20 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Information and Records Management Branch (MNBB–7714), U.S. Nuclear Regulatory Commission, Washington, DC 20555; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB–3019, (3150–0036 and 3150–0027) Office of Management and Budget, Washington, DC 20503.

Regulatory Analysis

Existing NRC regulations provide strong regulatory control over the export of strategic nuclear material from a national security (nonproliferation) standpoint, but provide much less control over non-strategic nuclear materials. Many such non-strategic imports and exports qualify for general licenses without specific review or approval by the NRC. (Domestic regulations in the U.S. and abroad, and international transportation regulations, provide the primary regulatory controls for health and safety and environmental protection purposes.) In fact, the Commission has taken the position in the Philippine Reactor Export Case, and in several materials export licensing cases, that its consideration of health, safety, and environmental impacts of an export is confined to those that affect the territory of the U.S. or the global commons and that the NRC is without jurisdiction to consider impacts upon the citizens of recipient nations. This position was upheld by the U.S. Court of Appeals for the District of Columbia Circuit in *NRDC* v. *NRC*, 647 F.2nd 1345 (D.C. Cir. 1981). Executive Order 12114, however, calls for concise environmental reviews by the Executive Branch of any exported reactor or nuclear waste management facility.

National and worldwide concerns about radioactive waste disposal practices have brought attention to the limited focus of the NRC's import and export regulations and the fact that certain types and quantities of radioactive materials, including possible shipments of low-level wastes, may be imported or exported without specific authorization by the NRC and without the NRC's knowledge. The voluntary international Code of Practice on the International Transboundary Movement of Radioactive Waste, which was approved by the IAEA General Conference in 1990 with strong U.S. Government support, provides that exports and international shipments of radioactive wastes which take place only with the prior notification and consent of the sending, receiving, and transit countries. The proposed changes in the NRC's regulations in Part 110 would serve to bring the U.S. into line with these international recommendations.

To the NRC's knowledge, there is no appreciable U.S. import or export traffic in radioactive waste. A possible exception, depending on one's definition of radioactive waste, would be the widely accepted practice, usually rooted in a sales or leasing contract or other agreement, of returning depleted sealed radioactive sources, used gauges, and other instruments containing radioactive materials, and similar medical and industrial items, to the original supplier-manufacturer for recycle or disposal. This practice is generally encouraged by governmental authorities as a way of helping to ensure that the items are handled in a responsible manner at the end of their useful life. By exempting these return shipments from new import or export controls, the NRC believes the proposed regulatory changes involve no significant cost to U.S. companies, the medical community, or other entities which provide or use nuclear equipment and materials. The changes could affect waste management companies interested in receiving low-level waste imports from other countries. At present low-level imports would be generally licensed under part 110. Under the proposed changes, the imports would require specific import licenses from the NRC and might not satisfy the licensing criteria. However, it is not clear whether this licensing requirement would impose any more difficult obstacle to a prospective waste importer than would the authority given the States and low-level waste Compacts under the LLRWPAA to block shipments of LLW into their respective jurisdictions.

Finally, it is noted that legislation to implement the Basel Convention on the Control of Transboundary Movements of Hazardous Waste (1989) may establish an interface in the regulatory import-export control regimes of the Environmental Protection Agency (EPA) and the NRC. That legislation may exempt from the EPA's control regime radioactive waste imports and exports controlled by the NRC in its implementation of the IAEA voluntary Code of Practice on Transboundary Movement of Radioactive Wastes.

In this sense, the alternative to the proposed changes to the NRC's regulations contained in this rulemaking is not to maintain the status quo but, arguably, some form of EPA control.

Overall, the NRC believes that requiring specific NRC licensing of U.S. waste imports and exports is a sound regulatory approach to help ensure that the transactions are subject to approval of the U.S. Government and the consent of other involved parties. This approach will bring the NRC's regulations in line with the recently-adopted IAEA voluntary Code of Practice. The following points influenced the NRC's position on this matter:

A. Only Option 1 of the ANPR, i.e., to continue the use of existing regulations, would not require rulemaking and this option is not acceptable if additional control over imports and exports of radioactive wastes is to be achieved.

B. The international community, including the United States, is committed to establishing a regime to ensure that waste imports and exports do not take place without the consent of the sending, receiving, and transit countries.

C. Specific licensing of radioactive waste exports and imports is a practical means of extending NRC cognizance and control over these transactions while also allowing for consultations and coordination with Executive Branch, State, and local authorities, as

appropriate. Formal Executive Branch coordination would require the Department of State to determine if each proposed radioactive waste export from the United States is acceptable to the government of the receiving country.

D. Sealed sources (and other shipments of source, byproduct, and special nuclear material currently exported or imported under NRC part 110 general licenses) should be allowed to return to a consignee in the country of origin who is authorized to possess them, without need for a specific import or export license from the NRC, in order to avoid undue disruption of commercial activities that embody desirable waste-takeback features.

The proposed rule would ensure that the NRC regulates imported, foreign-generated waste in a manner consistent with the NRC's regulation of domestically-generated waste. By requiring a specific import license from the NRC, the proposed rule would ensure that NRC regulatory requirements would be applicable to any imported radioactive waste resulting from any foreign nuclear operation that, if operated domestically, would be subject to the NRC's licensing jurisdiction.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. The new licensing requirements for radioactive waste specifically exclude from additional controls the return of U.S.-origin sealed sources by foreign customers, which is the principal type of existing commercial activity which otherwise might have been adversely affected. In all, the proposed amendments of the general licenses contained in part 110 are expected to result in fewer than ten new export and import licenses per year.

Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this proposed rule, and, therefore, a backfit analysis is not required.

List of Subjects in 10 CFR Part 110

Administrative practice and procedure, Classified information, Criminal penalties, Export, Import, Incorporation by reference, Intergovernmental relations, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements, Scientific equipment.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR part 110.

PART 110—EXPORT AND IMPORT OF NUCLEAR EQUIPMENT AND MATERIAL

1. The authority citation for part 110 continues to read:

Authority: Secs. 51, 53, 54, 57, 63, 64, 65, 81, 82, 103, 104, 109, 111, 126, 127, 128, 129, 161, 181, 182, 183, 187, 189, 68 Stat. 929, 930, 931, 932, 933, 936, 937, 948, 953, 954, 955, 956, as amended (42 U.S.C. 2071, 2073, 2074, 2077, 2092–2095, 2111, 2112, 2133, 2134, 2139, 2139a, 2141, 2154–2158, 2201, 2231–2233, 2237, 2239); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

Section 110.1(b)(2) also issued under Pub. L. 96–92, 93 Stat. 710 (22 U.S.C. 2403). § 110.11 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152) and secs. 54c and 57d., 88 Stat. 473, 475, (42 U.S.C. 2074). Section 110.27 also issued under sec. 309(a), Pub. L. 99–440. Section 110.50(b)(3) also issued under sec. 123, 92 Stat. 142 (42 U.S.C. 2153). Section 110.51 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234); Section 110.52 also issued under sec. 186, 68 Stat. 955 (42 U.S.C. 2236). Sections 110.80–110.113 also issued under 5 U.S.C. 552, 554. Sections 110.30–110.35 also issued under 5 U.S.C. 553.

For purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273), §§ 110.20–110.29, 110.50, §§ 110.120–110.129 also issued under secs. 161b. and i; 68 Stat. 948, 949, as amended (42 U.S.C. 2201(b) and (i)); and § 110.7b. as issued under sec. 161i, 68 Stat. 949, as amended (42 U.S.C. 2201(i) and §§ 110.7a and 110.53 are also issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

2. Section 110.2 is amended to add the terms *country of origin* and *radioactive waste* to read as follows:

§ 110.2 Definitions.

As used in this part,

* * * * *

Country of origin means the country which has previously exported specified radioactive materials to another country.

* * * * *

Radioactive waste means any material that contains or is contaminated with source material, special nuclear material or byproduct material, for which no use is foreseen, and any other imported radioactive material resulting from any foreign nuclear operation that, if operated in the United States, would be subject to the NRC's licensing authority, and for which no use is foreseen.

* * * * *

3. In § 110.21, the introductory text of paragraphs (a) and (b) are revised, and a new paragraph (c) is added to read as follows:

§ 110.21 Export of special nuclear material.

(a) Except as provided in paragraph (c) of this section, a general license is issued to any person to export the following to any country not listed in § 110.28:

* * * * *

(b) Except as provided in paragraph (c) of this section, a general license is issued to any person to export the following to any country not listed in § 110.28 or § 110.29:

* * * * *

(c) The general licenses in paragraphs (a) and (b) in this section do not authorize the export of special nuclear material in radioactive waste, other than special nuclear material in radioactive waste that is being returned to the country of origin to a consignee who is authorized by such country to possess the material.

4. In § 110.22, paragraph (a) introductory text, and paragraphs (b) and (c) are revised and a new paragraph (d) is added to read as follows:

§ 110.22 Export of source material.

(a) Except as provided in paragraph (d) of this section, a general license is issued to any person to export the following to any country not listed in § 110.28:

* * * * *

(b) Except as provided in paragraph (d) of this section, a general license is issued to any person to export uranium or thorium in individual shipments of 10 kilograms or less to any country not listed in § 110.28 or § 110.29. A person may not export more than 1,000 kilograms per year to any one country.

(c) Except as provided in paragraph (d) of this section, a general license is issued to any person to export uranium or thorium in individual shipments of 1 kilogram or less to any country listed in § 110.29. A person may not export more than 100 kilograms per year to any one country.

(d) The general licenses in paragraphs (a), (b), and (c) of this section do not authorize the export of source material in radioactive waste, other than source material in radioactive waste that is being returned to the country of origin to a consignee who is authorized by such country to possess the material.

5. In § 110.23, the introductory text of paragraphs (a) and (b), and paragraph

(c) are revised and a new paragraph (d) is added to read as follows:

§ 110.23 Export of byproduct material.

(a) Except as provided in paragraph (d) of this section, a general license is issued to any person to export the following to any country not listed in § 110.28:

* * * * *

(b) Except as provided in paragraph (d) of this section, a general license is issued to any person to export americium-241 to any country not listed in § 110.28, except that exports of americium-241 exceeding 1 curie per shipment or 100 curies per year to any country listed in § 110.29:

* * * * *

(c) Except as provided in paragraph (d) of this section, a general license is issued to any person to export bulk, undispersed tritium in individual shipments of 100 curies or less to any country not listed in § 110.28 or § 110.29. No person may export more than 10,000 curies per year to any one country.

(d) The general licenses in paragraphs (a), (b), and (c) of this section do not authorize the export of byproduct material in radioactive waste, other than byproduct material in radioactive waste that is being returned to the country of origin to a consignee who is authorized by such country to possess the material.

6. In § 110.27, paragraph (b) is revised to read as follows:

§ 110.27 Imports.

* * * * *

(b) The general license in paragraph (a) of this section does not authorize the import of source or special nuclear material in the form of irradiated fuel that exceeds 100 kilograms per shipment or the import of radioactive waste, other than radioactive waste that is being returned to the United States to a consignee who is authorized by the NRC or an NRC Agreement State to possess the material or to a United States Government or military facility which is authorized to possess the material.

* * * * *

7. In § 110.31, paragraph (f)(5) is redesignated as paragraph (f)(6) and a new paragraph (f)(5) is added to read as follows:

§ 110.31 Information required in license applications.

(f) * * *

* * * * *

(5) For proposed exports or imports of radioactive waste, the volume, classification, and physical and chemical characteristics of the material; and for proposed imports of radioactive waste, the industrial or other process responsible for generation of the waste, the ultimate disposition of the waste, and the status of the arrangements for that disposition, i.e., agreement by a Regional Low-Level Waste Compact or state to accept the material for disposal.

* * * * *

8. In § 110.40, paragraphs (b) and (c) are redesignated (c) and (d), respectively, and a new paragraph (b) is added to read as follows:

§ 110.40 Commission review.

* * * * *

(b) The Commission shall review an application to import or export radioactive waste.

* * * * *

9. In § 110.41, paragraphs (a)(7) and (a)(8) are redesignated as paragraphs (a)(8) and (a)(9), and a new paragraph (a)(7) is added to read as follows:

§ 110.41 Executive branch review.

(a) * * *

(7) An export involving radioactive waste.

* * * * *

10. In § 110.44, paragraph (c) is revised to read as follows:

§ 110.44 Issuance or denial of licenses.

* * * * *

(c) If, after receiving the Executive Branch judgment that the issuance of a proposed export license will not be inimical to the common defense and security, the Commission does not issue the proposed license on a timely basis because it is unable to make the statutory determinations required under the Atomic Energy Act, the Commission will publicly issue a decision to that effect and will submit the license application to the President. The Commission's decision will include an explanation of the basis for the decision and any dissenting or separate views. The provisions in this paragraph do not apply to Commission decisions regarding license applications for the export of byproduct material or radioactive waste.

* * * * *

11. In § 110.70, paragraph (c) is redesignated as paragraph (d), and new paragraphs (b)(4) and (c) are added to read as follows:

§ 110.70 Public notice of receipt of an application.

* * * * *

(b) * * *

(4) Radioactive waste.

(c) The Commission will also publish in the **Federal Register** a notice of receipt of an application for a license to import radioactive waste.

* * * * *

Dated at Rockville, MD, this 22nd day of April 1992.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 92-9828 Filed 4-27-92; 8:45 am]

BILLING CODE 7590-01-M

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 330

RIN 3064-AA73

Review of Rights and Capacities

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Advance notice of proposed rulemaking; request for comment.

SUMMARY: The Federal Deposit Insurance Corporation ("FDIC") is soliciting public comment on the rights and capacities in which deposit accounts are maintained and for which the FDIC provides deposit insurance coverage. This action is being taken to assist the FDIC in complying with the provision of the Federal Deposit Insurance Corporation Improvement Act of 1991 (the "Improvement Act") which requires a review of such rights and capacities.

DATES: Written comments must be received on or before June 29, 1992.

ADDRESSES: Written comments should be addressed to the Office of the Executive Secretary, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429. Comments may be hand-delivered to Room F-400, 1776 F Street, NW., Washington, DC 20429, on business days between 8:30 a.m. and 5 p.m. Comments may also be inspected in room F-402 between 8:30 a.m. and 5 p.m. on business days. [FAX number: (202) 898-3838]

FOR FURTHER INFORMATION CONTACT: Jay Golter, Financial Analyst, Division of Research and Statistics, (202) 898-3924, or Claude A. Rollin, Counsel, Legal Division, (202) 898-3985, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC, 20429.

SUPPLEMENTARY INFORMATION: Section 311 of the Improvement Act provides that, during the one-year period after its enactment, the FDIC shall conduct a review of the rights and capacities in which deposit accounts are maintained and for which deposit insurance coverage is provided. The Improvement

Act further indicates that after the one-year review period the FDIC may prescribe regulations that provide for separate deposit insurance coverage for accounts held in different capacities and rights. Such separate coverage can be provided only if the FDIC Board of Directors determine that it is consistent with (1) the purposes of protecting small depositors and limiting the undue expansion of deposit insurance coverage; and (2) the insurance provisions of the Federal Deposit Insurance Act. In an effort to comply with the requirements of the Improvement Act and to obtain practical and helpful information, the FDIC is hereby requesting public comment on the rights and capacities described in the FDIC's existing deposit insurance regulations which are published at 12 CFR part 330.

Under the FDIC's existing deposit insurance regulations, deposit insurance is based upon the ownership rights and capacities in which deposit accounts are maintained at insured depository institutions. All deposits maintained in the same right and capacity (*i.e.*, owned in the same manner) in one insured institution are added together and insured up to $100,000 in the aggregate. All deposits maintained in different rights and capacities, as recognized under the FDIC's regulations, are separately insured from each other, provided that all of the requirements of the regulations are satisfied.

For example, if a depositor maintains two individual (single ownership) accounts at an insured institution those accounts would be added together and insured up to $100,000 in the aggregate since they are maintained in the same right and capacity. However, if a depositor has an individual account and a joint account with another person at the same insured institution, those accounts would be insured separately, up to $100,000 each, provided that all regulatory requirements are satisfied, since they are being held in different rights and capacities (*i.e.*, owned in different manners).

The different types of accounts which reflect the different rights and capacities in which funds are owned and may be separately insured under the existing regulations include the following: (1) Individual accounts; (2) joint accounts; (3) revocable trust accounts; (4) irrevocable trust accounts; (5) accounts of a corporation, partnership or unincorporated association; (6) accounts held by insured depository institutions in a fiduciary capacity; (7) employee benefit plan accounts; (8) IRA & Keogh accounts; (9) public unit accounts.

In addition to any general comments on these rights and capacities, the FDIC asks that commenters consider the following specific questions in responding to this request:

(1) How might the term "rights and capacities" be redefined in order to better protect small depositors or otherwise increase fairness in access to deposit insurance coverage?

(2) What are the potential consequences of eliminating the separate insurance coverage that currently exists for some or all of the specific rights and capacities?

(3) How might the rights and capacities concept under the current regulation be simplified in order to (a) reduce possible confusion and misunderstanding by employees and customers of financial institutions and (b) increase the level of depositor discipline in the financial system?

(4) What, if any, additional rights and capacities should be recognized for deposit insurance purposes?

(5) How might existing rights and capacities be limited while still protecting small depositors?

(6) Should deposit insurance be determined by reference to social security numbers or other taxpayer identification numbers?

By Order of the Board of Directors.

Dated at Washington, DC this 21st day of April, 1992.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[FR Doc. 92-9753 Filed 4-27-92; 8:45 am]

BILLING CODE 6714-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Ch. I

[Docket No. RM91-10-000]

Regulations Governing Ex Parte Communications; Public Conference

April 13, 1992.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of public conference.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is rescheduling the public conference in the above-mentioned proceeding for May 19, 1992. The previous notice scheduling this conference was issued March 20, 1992 (57 FR 10622, March 27, 1992). The public conference will afford interested persons an opportunity to discuss with the Commission and the staff revision of its *ex parte* regulations.

DATES: The public conference will be held on Tuesday, May 19, 1992, at 10 a.m. Requests to participate should be received by the Commission on or before May 5, 1992.

ADDRESSES: The conference will be held in the Commission's Hearing Room Number 1, 810 First Street, NE., Washington, DC. All requests to participate should identify the name of the speaker, the group represented, refer to Docket No. RM91-10-000 and be addressed to: Office of the Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426.

FOR FURTHER INFORMATION CONTACT: Michael Schopf, Associate General Counsel, Enforcement and General & Administrative Law, Federal Energy Regulatory, 825 North Capitol Street NE., Washington, DC 20426 (202) 208-0597.

SUPPLEMENTARY INFORMATION: In addition to publishing the full text of this document in the **Federal Register**, the Commission also provides all interested persons an opportunity to inspect and copy the contents of this document during normal business hours in room 3308, 941 North Capitol Street NE., Washington, DC 20426.

The Commission Issuance Posting System (CIPS), an electronic bulletin board service, provides access to the text of formal documents issued by the Commission. CIPS is available at no charge to the user and may be accessed using a personal computer with a modem by dialing (202) 208-1397. To access CIPS, set communications software to use 300, 1200 or 2400 baud, full duplex, no parity, 8 data bits, and 1 stop bit. The full text of this notice will be available on CIPS for 30 days from the date of issuance. The complete text on diskette in WordPerfect format may also be purchased from the Commission's copy contractor, LaDorn Systems Corporation, also located in room 3308, 941 North Capitol Street NE., Washington, DC.

Lois D. Cashell,

Secretary.

[FR Doc. 92-9836 Filed 4-27-92; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Ch. I

Management Systems; Highway Safety

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of public workshops.

SUMMARY: The FHWA announces that it will hold three 1-day public workshops on the development, establishment, and implementation of a Highway Safety Management System. The workshops will address such issues as system scope, application, documentation, certification, and implementation. In addition, coordination and participation among State and local organizations and institutional issues and concerns will be explored.

DATES: The workshops will be conducted between 9 a.m. and 4 p.m. (local time) at the following locations and dates:

May 29, 1992, Nassif Building, 400 Seventh Street SW., room 2230, Washington, DC 20590.

June 1, 1992, Environmental Protection Agency Building, 75 Hawthorne Street, American Samoa Room, San Francisco, California 94105.

June 10, 1992, United Labor Building, 6301 Rockhill Road, 1st Floor Conference Room, Kansas City, Missouri 64141.

FOR FURTHER INFORMATION CONTACT: Mr. Fred Small, Office of Highway Safety (HHS-21), (202) 366-2171, or Mr. Wilbert Baccus, Office of Chief Counsel (HCC-32), (202) 366-0780, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590. Office hours are 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except legal holidays.

SUPPLEMENTARY INFORMATION: Section 1034 of Public Law 102-240, 105 Stat. 1914, the Intermodal Surface Transportation Efficiency Act (ISTEA) of 1991 amended title 23, United States Code, Highways (23 U.S.C.) by adding new section 303 (23 U.S.C. 303), Management Systems, which requires the Secretary of Transportation (the Secretary) to issue regulations, within one year after the date of enactment (by December 18, 1992) for State development, establishment, and implementation of six management systems, one of which is Highway Safety. The FHWA intends to initiate rulemaking shortly to implement section 1034. Notes of the workshops announced in this notice will be placed in the rulemaking docket.

Workshop Procedures: The following procedures have been established to facilitate the workshops:

1. The workshops will include presentations and discussions on identified issues by a panel of representatives of nationally recognized groups, organizations, agencies or associations with an interest in highway safety.

2. Persons, either as an individual or representative of any group, organization, agency or association, are encouraged to direct questions to the panel following each issue presentation.

3. Written statements from interested persons will be accepted at the workshops and a copy of each written statement will be placed in the rulemaking docket.

4. Oral statements will be received from the public following the panel sessions as time permits. All speakers exclusive of the panel members will be limited to a 5-minute statement, to provide an opportunity for a wide variety of individuals to make statements at the workshops.

5. Any statements made by the workshop officer or any member of the workshop panel to clarify issues during the workshop should not be construed as the position of the FHWA with respect to the rulemaking proceeding.

6. A summary will be made of each workshop and any material accepted during the workshop, to be included in the record, will be included in FHWA No. 92-14.

7. The workshops are designed to solicit public views and information on the implementation of section 1034. Therefore, the workshops will be conducted in an informal and nonadversarial manner. The workshop officer is entitled to ask questions in order to clarify any statement made at the hearing or the material accepted by the workshop officer during the workshops.

Authority: 23 U.S.C. 303 and 315; 49 CFR 1.48 and 1.51; 49 U.S.C. App. 1607.

Issued on: April 20, 1992.

T.D. Larson,

Administrator.

[FR Doc. 92-9807 Filed 4-27-92; 8:45 am]

BILLING CODE 4910-22-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[OAQPS # CA-14-11-5422; FRL-4127-3]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision; San Joaquin Valley Unified Air Pollution Control District Kern County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking.

SUMMARY: EPA is proposing to approve revisions to the California State Implementation Plan (SIP) adopted by the San Joaquin Valley Unified Air Pollution Control District (SJVUAPCD) and the Kern County Air Pollution Control District (KCAPCD) on April 11, 1991 and May 6, 1991, respectively. The California Air Resources Board submitted these revisions to EPA on May 30, 1991. The revisions concern the adoption of SJVUAPCD's Rule 464.1, Valves, Pressure Relief Valves, Flanges, Threaded Connections and Process Drains at Petroleum Refineries and Chemical Plants; SJVUAPCD's rule 464.2, Pump and Compressor Seals at Petroleum Refineries and Chemical Plants; KCAPCD's rule 414.1, Valves, Pressure Relief Valves, Flanges, Threaded Connections and Process Drains at Petroleum Refineries and Chemical Plants; and KCAPCD's rule 414.5, Pump and Compressor Seals at Petroleum Refineries and Chemical Plants. All of these rules control equipment leaks of volatile organic compounds (VOCs) at refineries and chemical plants. EPA has evaluated each of these rules and is proposing to approve them under section 110(k)(3) as meeting the requirements of section 110(a) and part D of the Clean Air Act, as amended in 1990 (CAA or the Act).

DATES: Comments must be received on or before May 28, 1992.

ADDRESSES: Comments may be mailed to: Esther Hill, Northern California, Nevada and Hawaii Rulemaking Section (A-5-4), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

Copies of the rule revisions and EPA's evaluation report of each rule are available for public inspection at EPA's Region 9 office during normal business hours. Copies of the submitted rule revisions are also available for inspection at the following locations:

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 1219 "K" Street, Sacramento, CA 95814.
San Joaquin Valley Unified Air Pollution Control District, 1745 West Shaw, suite 104, Fresno, CA 93711.
Kern County Air Pollution Control District, 2700 M Street, suite 275, Bakersfield, CA 93301.

FOR FURTHER INFORMATION CONTACT: Doris Lo, Northern California, Nevada and Hawaii Rulemaking Section (A-5-4), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105. Telephone: (415) 744-1187, FTS: 484-1187.

SUPPLEMENTARY INFORMATION:

Background

On March 3, 1978, EPA promulgated a list of ozone nonattainment areas under the provisions of the Clean Air Act, as amended in 1977 (1977 CAA), that included the following eight air pollution control districts (APCDs): Fresno County APCD, Kern County APCD,[1] Kings County APCD, Madera County APCD, Merced County APCD, San Joaquin County APCD, Stanislaus County APCD, and Tulare County APCD. 43 FR 8964, 40 CFR 81.305. Because these areas were unable to meet the statutory attainment date of December 31, 1982, California requested under section 172(a)(2), and EPA approved, an extension of the attainment date to December 31, 1987.[2] 40 CFR 52.238. On May 26, 1988, EPA notified the Governor of California that the above districts' portions of the California State Implementation Plan (SIP) were inadequate to attain and maintain the ozone standard and requested that deficiencies in the existing SIP be corrected (EPA's SIP-Call). On November 15, 1990, the Clean Air Act Amendments of 1990 were enacted. Pub. L. 101-549, 104 Stat. 2399, codified at 42 U.S.C. 7401-7671q. In amended section 182(a)(2)(A) of the CAA, Congress statutorily adopted the requirement that nonattainment areas fix their deficient reasonably available control technology (RACT) rules for ozone and established a deadline of May 15, 1991 for states to submit corrections of those deficiencies.

On March 20, 1991, the San Joaquin Valley Unified Air Pollution Control District (SJVUAPCD) was formed. The SJVUAPCD has authority over the San Joaquin Valley Air Basin which includes all of the above eight counties except for the Southeast Desert Air Basin portion of Kern County. Thus, Kern County Air Pollution Control District (KCAPCD) still exists, but only has authority over the Southeast Desert Air Basin portion of Kern County.

Section 182(a)(2)(A) applies to pre-amendment section 107 non-attainment areas that were again designated nonattainment upon enactment of the Clean Air Act Amendments of 1990 and classified as marginal or above under section 181(a)(1) by operation of law. Such areas must adopt and correct RACT rules pursuasnt to pre-amended section 172(b) as interpreted in pre-amendment guidance.[3] EPA's SIP-Call used that guidance to indicate the necessary corrections for specific nonattainment areas. APCDs found in the San Joaquin Valley Air Basin (now collectively known as the SJVUAPCD) were subject to the RACT fix-up requirement and the May 15, 1991 deadline.[4] KCAPCD was subject to EPA's SIP-Call, but was not subject to the RACT fix-up requirement and the May 15, 1991 deadline.[5]

The State of California submitted many revised RACT rules for incorporation into its SIP on May 30, 1991, including the rules being acted on in this notice. This notice addresses EPA's proposed action for SJVUAPCD's rule 464.1, Valves, Pressure Relief Valves, Flanges, Threaded Connections and Process Drains at Petroleum Refineries and Chemical Plants; SJVUAPCD's rule 464.2, Pump and Compressor Seals at Petroleum Refineries and Chemical Plants; KCAPCD's rule 414.1, Valves, Pressure Relief Valves, Flanges, Threaded Connections and Process Drains at Petroleum Refineries and Chemical Plants; and KCAPCD's rule 414.5, Pump and Compressor Seals at Petroleum Refineries and Chemical Plants. These submitted rules were found to be complete on July 10, 1991 pursuant to EPA's completeness criteria set forth in 40 CFR part 51 appendix V [6] and are being proposed for approval into the SIP.

All four rules control the emission of VOCs from leaking equipment at petroleum refineries and chemical plants. VOCs contribute to the production of ground level ozone and smog. The rules were adopted as part of each district's efforts for ozone and in response to EPA's SIP-Call and the section 182(a)(2)(A) CAA requirement. The following is EPA's evaluation and proposed action for these four rules.

EPA Evaluation and Proposed Action

In determining the approvability of a VOC rule, EPA must evaluate the rule for consistency with the requirements of the CAA and EPA regulations, as found in section 110 and part D of the CAA and 40 CFR part 51 (Requirements for Preparation, Adoption, and Submittal of Implementation Plans). The EPA interpretation of these requirements, which forms the basis for today's action, appears in the various EPA policy guidance documents listed in footnote 3. Among those provisions is the requirement that a VOC rule must, at a minimum, provide for the implementation of RACT for stationary sources of VOC emissions. This requirement was carried forth from the pre-amended Act.

For the purpose of assisting state and local agencies in developing RACT rules, EPA prepared a series of Control Technique Guideline (CTG) documents. The CTGs are based on the underlying requirements of the Act and specify the presumptive norms for what is RACT for specific source categories. Under the CAA, Congress ratified EPA's use of these documents, as well as other Agency policy, for requiring States to "fix-up" their RACT rules. See section 182(a)(2)(A). The CTG applicable to all of these rules is entitled, "Control of

[1] At that time, Kern County included portions of two air basins: The San Joaquin Valley Air Basin and the Southeast Desert Air Basin. The San Joaquin Valley Air Basin portion of Kern County was designated as nonattainment, and the Southeast Desert Air Basin portion of Kern County was designated as unclassified. See 40 CFR 81.305 (1991).

[2] This extension was not requested for Kern County. Thus, Kern County's attainment date remained December 31, 1982.

[3] Among other things, the pre-amendment guidance consists of those portions of the proposed Post-1987 ozone and carbon monoxide policy that concern RACT, 52 FR 45044 (November 24, 1987); "Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations, Clarification to Appendix D of November 24, 1987 **Federal Register** Notice" (Blue Book) (notice of availability was published in the **Federal Register** on May 25, 1988); and the existing control technique guidelines (CTGs).

[4] The San Joaquin Valley Air Basin was again designated nonattainment and classified as serious by operation of law pursuant to section 107(d) and section 181(a) upon the date of enactment of the Clean Air Act Amendments of 1990. See 56 FR 56694 (November 6, 1991).

[5] KCAPCD was not subject to the RACT fix-up requirement and the May 15, 1991 deadline because the Southeast Desert Air Basin portion of Kern County was not a pre-enactment nonattainment area, and thus, was not automatically designated nonattainment on the date of enactment of the Clean Air Act Amendments of 1990. (See section 107(d) and section 182(a)(2)(A) of the Clean Air Act Amendments of 1990.) However, the KCAPCD is still subject to the requirements of EPA's SIP-Call because the SIP-Call included *all* of Kern County. The substantive requirements of the SIP-Call are the same as those of the statutory RACT fix-up requirement.

[6] EPA has since adopted completeness criteria pursuant to section 110(k)(1)(A) of the CAA. See 56 FR 42216 (August 26, 1991). These will replace the completeness criteria currently set forth in 40 CFR part 51, appendix V.

Volatile Organic Compound Lakes from Synthetic Organic Chemical and Polymer Manufacturing Equipment", EPA, document #EPA-450/3-83-006. Further interpretations of EPA policy are found in the Blue Book, referred to in footnote 3. In general, these guidance documents have been set forth to ensure that VOC rules are fully enforceable and strength or maintain the SIP.

SJVUAPCD's submitted rule 464.1 is a revision of existing SIP approved rules from three of the eight districts which combined to form SJVUAPCD. The three SIP approved rules were Kern APCD's rule 414.1, Valves, Pressure Relief Valves and Flanges at Petroleum Refineries and Chemical Plants; Kings County APCD's rule 414.1, valves and Flanges at Petroleum Refineries and Chemical Plants; and San Joaquin County APCD's rule 413.1, Valves and Flanges at Petroleum Refineries and Chemical Plants. KCAPCD's submitted rule 414.1 is a revision of KCAPCD's rule 414.1 Valves, Pressure Relief Valves and Flanges at Petroleum Refineries and Chemical Plants.

KCAPCD's submitted rule 414.1 and SJVUAPCD's submitted rule 464.1 are essentially identical rules. The rules require control of vapor leaks greater than 10,000 ppm and liquid leaks greater than three drops per minute. The rules include the following significant changes from the SIP approved rules:

—Expanded the scope of the rule to include control requirements for threaded connections and process drains.
—Added many new definitions to clarify and strengthen the rule.
—Expanded the definition of "volatile organic compound" so that more VOCs are controlled by the rule.
—Added a requirement for an operator management plan that describes how the requirements of the rule will be met.
—Added specific recordkeeping and test method requirements.

SJVUAPCD's submitted rule 464.2 is a new rule for seven of the eight districts which combined to form SJVUAPCD and is a revision of an existing SIP approved rule for Kings County. The SIP approved rules is Kings County APCD's rule 414.4, Pump and Compressor Seals at Petroleum Refineries. KCAPCD's submitted rule 414.5 is being proposed for the first time for inclusion into the SIP.

KCAPCD's submitted rule 414.5 and SJVUAPCD's submitted rule 464.2 are essentially identical rules. The rules require control of vapor leaks greater than 10,000 ppm and liquid leaks greater than three drops per minute. SJVUAPCD's submitted rule 464.2 includes the following significant changes from the King County APCD's SIP approved rule:

—Deleted an exemption for small pumps.
—Added requirements to control liquid leaks.
—Expanded the definition of "volatile organic compound" so that more VOCs are controlled by the rule.
—Increased the inspection frequency requirements for pumps from annual to quarterly inspections.
—Added a requirement for an operator management plan that describes how the requirements of the rule will be met.
—Added specific recordkeeping and test method requirements

EPA has evaluated the four submitted rules and has determined that they are consistent with the CAA, EPA regulations, and EPA policy. Therefore, SJVUAPCD's rule 464.1, SJVUAPCD's rule 464.2, KCAPD's rule 414.1, and KCAPCD's Rule 414.5 are being proposed for approval under section 110(k)(3) of the CAA as meeting the requirements of section 110(a) and part D.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any state implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

Regulatory Process

Under 5 U.S.C. section 605(b), I certify that this SIP revision will not have a significant economic impact on a substantial number of small entities. (See 46 FR 8709.)

This action has been classified as a Table 2 action by the **Federal Register** on January 19, 1989 (54 FR 2214–2225). EPA has submitted a request for a permanent waiver for Table 2 and Table 3 SIP revisions. OMB has agreed to continue the temporary waiver until such time as it rules on EPA's request.

List of Subjects in 40 CFR Part 52

Air pollution control, Ozone, Hydrocarbons, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401–7671q.

Dated: April 14, 1992.

John Wise,

Acting Regional Administrator.

[FR Doc. 92–9868 Filed 4–27–92; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 92-89, RM-7964]

Radio Broadcasting Services; Fosston, MN

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition filed by Pine to Prairie Broadcasting, Inc., proposing the substitution of Channel 296C2 for Channel 296A at Fosston, Minnesota, and modification of the license for Station KKCQ-FM to specify operation on the higher class channel. Canadian concurrence will be requested for this allotment at coordinates 47–37–46 and 95–38–02. In accordance with § 1.420(g) of the Commission's rules, we will not accept competing expressions of interest for the use of Channel 296C2 at Fosston or require petitioner to demonstrate the availability of an additional equivalent class channel for use by such parties.

DATES: Comments must be filed on or before June 12, 1992, and reply comments on or before June 29, 1992.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner's counsel, as follows: Eugene T. Smith, 715 G Street, SE., Washington, DC 20003.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rule Making, MM Docket No. 92–89, adopted April 8, 1992, and released April 22, 1992. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, Downtown Copy Center, 1714 21st Street NW., Washington, DC 20036, (202) 452–1422.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in

Commission proceedings, such as the one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contact.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Michael C. Ruger,

Acting Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 92-9891 Filed 4-27-92; 8:45 am]

BILLING CODE 6712-01-M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. 92-15; Notice 1]

RIN 2127-AE35

Federal Motor Vehicle Safety Standards Lamps, Reflective Devices, and Associated Equipment

AGENCY: National Highway Traffic Safety Administration, NHTSA (DOT).

ACTION: Notice of proposed rulemaking.

SUMMARY: This document grants a petition for rulemaking submitted by Motorcycle Industry Council, and proposes the deletion of the minimum 4-inch edge to edge separation distance between motorcycle turn signals and stop or taillamps. Implementation of the requested rulemaking would allow the use of designs in use elsewhere, thus no longer requiring a specialized design, at extra cost, for the U.S.

DATES: Comment closing date for the proposal is June 12, 1992. Any request for an extension of time in which to comment must be received not later than 10 days before that date (49 CFR 553.19). The amendment would be effective 180 days after publication of the final rule in the **Federal Register**.

ADDRESSES: Comments should refer to the docket number and notice number of this notice, and be submitted to: Docket Section, room 5109, 400 Seventh Street, SW., Washington, DC 20590. Docket hours are from 9:30 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT: Kenneth Hardie, Office of Rulemaking, 202-366-6987.

SUPPLEMENTARY INFORMATION: Table III of Standard No. 108 requires a motorcycle to be equipped with at least one stop lamp and one taillamp. Table IV requires that if a single lamp is used, it must be mounted on the motorcycle's vertical centerline. Table IV also requires that there be a minimum edge to edge separation distance of 4 inches between motorcycle turn signal lamps and a single tail or stop lamp. However, the agency has interpreted the minimum separation requirement as inapplicable when two stop lamps and/or taillamps are used, symmetrically disposed around the vertical centerline.

The Motorcycle Industry Council (MIC) has petitioned "to remove the requirement for a (4) inch minimum edge to edge separation distance * * *."MIC argues that the present requirement is, in effect, design restrictive, prohibiting use of lamp designs employed elsewhere in the world. MIC states that these interpretations preclude the installation of a modular unit such as a center mounted tail/stop lamp with adjacent turn signals, or integration of the rear lamp into the body panel design. The 4-inch requirement also limits the practical size of the tail/stop lamp, with the effect of limiting nighttime rear conspicuity. MIC notes that these configurations are allowed worldwide, except in the U.S. and Canada. It states that in Canada, rulemaking has been initiated to eliminate the 4-inch spacing requirement. Canada's rationale for its proposal is that the current 4-inch spacing limitation effectively prevents the use of integrated rear lamp assemblies which could contain large tail and stop lamps, thereby improving the rear conspicuity of the motorcycle. Canada also commented that experience with passenger cars has shown that adjacent turn signals and tail/stop lamps are easily perceptible.

Implementation of the requested rulemaking would allow the use of designs in use elsewhere, thus no longer requiring a specialized design, at extra cost, for the U.S. MIC also notes that, for harmonization purposes, current motorcycles are equipped with amber rear turn signal lamps. Further, a motorcycle fitted with amber rear turn signal lamps adjacent to a single centered red lamp would remain subject to the 9-inch spacing requirement. Thus, the requested rulemaking would not reduce the existing level of safety.

NHTSA has given careful consideration to MIC's petition and has granted it. NHTSA agrees that the signals from a motorcycle fitted with amber rear turn signal lamps adjacent to a single, centered red tail/stop lamp would be easily interpreted by following vehicles, and that such a configuration would not likely degrade the existing safety of the vehicle. This proposed amendment is consistent with the agency's policy to remove design restrictions not needed for safety, and with the policy of international harmonization.

However, MIC's request and comment leave NHTSA unsure whether MIC is requesting the limitation of the requirement as it applies to amber turn signal lamps only, or the total elimination of the requirement, regardless of the color. NHTSA therefore decided to evaluate each alternative, and has tentatively concluded that the deletion of the 4-inch spacing requirement for amber turn signal lamps ought not to have a negative effect upon safety. However, NHTSA has also tentatively concluded that the 4-inch spacing requirement should be maintained for red turn signal lamps when the stop/taillamp are mounted on the vertical centerline. Maintaining the existing requirement of more than 20 years standing will ensure that there is no masking of the light from one red lamp by the light from another, impairing the information that each seeks to impart.

However, there is an alternative that interests NHTSA: eliminating both the 4-inch spacing requirement and the use of red as a permissible alternative to amber for rear motorcycle turn signal lamps. It appears that none of the MIC member companies manufacture motorcycles with red rear turn signal lamps. Nor does Harley-Davidson, a non-MIC company. The use of amber is mandated in Europe. Therefore, as an alternative, NHTSA is proposing an amendment of Table III to specify only amber, and of Table IV to specify only amber and to remove the 4-inch limit.

Effective Date

Because the proposed amendment would relieve a restriction and create no additional burden upon any regulated party, it is tentatively found that good cause is shown for an effective date earlier than 180 days after issuance of a rule based upon this proposal. Accordingly, the effective date would be 30 days after publication of the final rule in the **Federal Register**.

Rulemaking Analyses

Executive Order 12291 (Federal Regulation) and DOT Regulatory Policies and Procedures

NHTSA has considered the impacts of this rulemaking action and has determined that it is not major within the meaning of Executive Order 12291 "Federal Regulation", or significant under Department of Transportation regulatory policies and procedures.

Providing manufacturers with the option of locating amber turn signal lamps closer to stop/taillamps mounted on the vertical centerline would permit either modular units equipped with stop, tail and turn signal lamps, or integration of the rear lamps into the body panel. Because of uncertainties regarding the designs, savings per vehicle, and the number of vehicles that would be manufactured to take advantage of the relaxation, NHTSA is unable to quantify the potential cost reduction associated with this rulemaking action. However, the design flexibility that an amendment would afford should yield some small manufacturing cost savings which could be passed on to consumers. Tooling costs could be reduced for modular and integrated rear lighting systems. Also, fewer and simpler steps in the vehicle assembly process could result in reduced labor costs. Finally, greater production economies of scale could be achieved since regulatory requirements would be internationally harmonized.

Regulatory Flexibility Act

The agency has also considered the effects of this rulemaking action in relation to the Regulatory Flexibility Act. For the reasons noted above, I certify that this rulemaking action would not have a significant economic effect upon a substantial number of small entities. Motorcycle manufacturers are generally not small businesses within the meaning of Regulatory Flexibility Act. Further, small organizations and governmental jurisdictions would not be significantly affected as the price of new motorcycles should not be more than minimally impacted. Accordingly, no Regulatory Flexibility Analysis has been prepared.

Executive Order 12612 (Federalism)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612 "Federalism". It has been determined that the rulemaking action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

National Environmental Policy Act

NHTSA has analyzed this rulemaking action for purposes of the National Environmental Policy Act. The proposed rule would not have a significant effect upon the environment, as it would not change the equipment currently required for motorcycles.

Request for Comments

Interested persons are invited to submit comments on the proposal. It is requested but not required that 10 copies be submitted.

All comments must not exceed 15 pages in length. (49 CFR 553.21). Necessary attachments may be appended to these submissions without regard to the 15-page limit. This limitation is intended to encourage commenters to detail their primary arguments in a concise fashion.

If a commenter wishes to submit certain information under a claim of confidentiality, three copies of the complete submission, including purportedly confidential business information, should be submitted to the Chief Counsel, NHTSA, at the street address given above, and seven copies from which the purportedly confidential information has been deleted should be submitted to the Docket Section. A request for confidentiality should be accompanied by a cover letter setting forth the information specified in the agency's confidential business information regulation. 49 CFR part 512.

All comments received before the close of business on the comment closing date indicated above for the proposal will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Comments received too late for consideration in regard to the final rule will be considered as suggestions for further rulemaking action. Comments on the proposal will be available for inspection in the docket. The NHTSA will continue to file relevant information as it becomes available in the docket after the closing date, and it is recommended that interested persons continue to examine the docket for new material.

Those persons desiring to be notified upon receipt of their comments in the rules docket should enclose a self-addressed, stamped postcard in the envelope with their comments. Upon receiving the comments, the docket supervisor will return the postcard by mail.

List of Subjects in 49 CFR Part 571

Imports, Motor vehicle safety, Motor vehicles.

In consideration of the foregoing, it is proposed that 49 CFR part 571 be amended as follows:

PART 571—FEDERAL MOTOR VEHICLE SAFETY STANDARDS

1. The authority citation for part 571 continues to read as follows:

Authority: 15 U.S.C. 1392, 1401, 1403, 1407; delegation of authority at 49 CFR 1.50.

§ 571.108 [Amended]

2. Section 571.108 would be amended as follows:

Alternative 1

a. In Table IV, in the entry "Turn signal lamps", the second sentence in the second paragraph under the column headed "Motorcycles" would be revised to read: "Minimum edge to edge separation distance between lamp and tail or stop lamp is 4 inches, when a single stop and taillamp is installed on the vertical centerline, and the turn signal lamps are red."

Alternative 2

b. In Table III, in the entry "Turn signal lamps", the words "2 amber; 2 red or amber" in the column headed "Motorcycles", would be revised to read "2 amber; 2 amber."

c. In Table IV, in the entry "Turn signal lamps", in the second paragraph under the column heading "Motorcycles", the words "red or" in the first sentence would be removed, and the second sentence would be removed in its entirety.

Issued on: April 13, 1992.

Barry Felrice,

Associate Administrator for Rulemaking.

[FR Doc. 92-9817 Filed 4-27-92; 8:45 am]

BILLING CODE 4910-59-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 285

[Docket No. 920407-2107]

RIN 0648-AD01

Atlantic Tuna Fisheries; Bluefin Tuna

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Proposed rule.

SUMMARY: The Secretary of Commerce (Secretary) issues this proposed rule governing the Atlantic bluefin tuna (bluefin) fishery to: (1) Reduce the total U.S. quota allocation by 10 percent for the 2-year period 1992 through 1993; (2) spread the reduction equally over the years 1992 and 1993, except for subcategories of fisheries that have begun fishing already in 1992; (3) apply the annual harvest amount among the categories based on the average landings of each category during the period 1983 to 1990; (4) reduce the allowable catch of bluefin less than 115 cm (45 inches) to no more than 8 percent

of the annual U.S. allocation; (5) prohibit sale of bluefin less than 196 cm (77 inches); (6) implement area subquotas and differential bag limits in the Angling category for bluefin less than 115 cm (45 inches); (7) prohibit retention of young school bluefin (less than 66 cm (26 inches)); (8) preclude vessels permitted for other categories from fishing in the Angling category and Angling category vessels from fishing in other categories; (9) implement a mechanism to subtract quota overages from the appropriate category in following years if the United States exceeds its allocation; (10) eliminate the adjustment to multiple catches per day in the General category; and (11) make other technical changes to enhance administration and enforcement. This action is necessary to implement the recently adopted recommendations of the International Commission for the Conservation of Atlantic Tunas (ICCAT) and to improve management of bluefin tuna.

DATES: Comments on this proposed rule must be received on or before May 26, 1992.

ADDRESSES: Comments on the proposed rule should be sent to, and copies of the Environmental Assessment, Regulatory Impact Review and Initial Regulatory Flexibility Analysis are available from, Richard H. Schaefer, Director, Office of Fisheries Conservation and Management (F/CM), National Marine Fisheries Service (NMFS), 1335 East-West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Richard B. Stone, 301–713–2347.

SUPPLEMENTARY INFORMATION: The Atlantic bluefin tuna fishery is managed under the implementing regulations at 50 CFR part 285 under the authority of the Atlantic Tunas Convention Act (ATCA), 16 U.S.C. 971 *et seq.* The ATCA authorizes the Secretary to promulgate regulations as may be necessary to carry out the recommendations of ICCAT. The authority to implement the ICCAT recommendations is delegated from the Secretary to NMFS.

The Fishery Conservation Amendments of 1990 (FCA), Public Law 101–627, also authorize management of tunas under the Magnuson Fishery Conservation and Management Act (Magnuson Act). The Secretary proposes to issue regulations governing the fishery under the authority of the ATCA until such time as a fishery management plan is developed and complementary regulations are issued under the Magnuson Act.

Background

In 1981, ICCAT adopted stringent measures for the bluefin fishery in the western Atlantic that limited U.S. harvests to 605 mt and the total western Atlantic harvest to 1,160 mt. This represented a substantial reduction from previous harvest levels for the three nations involved: Japan, Canada and the United States (Contracting Parties). ICCAT based this action on the advice of the group's Standing Committee on Research and Statistics (SCRS) that concluded that the stock of adult fish had become depleted to very low levels and was expected to decrease further. SCRS, therefore, recommended a major reduction in catch to "as near zero as feasible" for the 1982 fishing year.

During the subsequent annual meeting, citing a need for improved data from the fishery, ICCAT increased the allowable harvest to 2,660 mt per year, where it has remained for the fishing years 1983 through 1991. The U.S. portion was 1,387 mt.

Domestic regulations to carry out the ICCAT recommendations were implemented in 1982 and 1983. At that time, there were several user groups participating in the fishery that are described in the 1982 Environmental Impact Statement (EIS). That document discussed the expected impacts of the ICCAT-imposed reductions on the environment, with particular focus on the participants. Several objectives were agreed to by the United States to guide the development of regulations and ensure consistency with the ATCA and other applicable U.S. law. The objectives were to: (1) Implement the ICCAT recommendations; (2) provide the data necessary for monitoring the status of the stock; (3) minimize economic displacement and preserve traditional fisheries; and (4) maximize the use of the available resource and spread the opportunity among as many users as possible. NMFS believes these objectives have been successful and remain applicable today.

Current Status of the Stock

Early in 1991, NMFS convened an independent panel of NMFS and outside scientists to discuss the status of the stock and assessment methods. This panel made several observations concerning the status of the western Atlantic bluefin stock:

1. That overall fishing mortality rates are at near record high levels for large and medium bluefin;

2. That the number of fish in the spawning stock is near record low levels;

3. That there has been a downward trend for the spawning stock since 1982;

4. That protection of strong recruiting year classes may do more to further recovery of the stock than adjustments in the annual catch quota; however, all year classes could produce substantially greater yield if fishing mortality were reduced; and

5. That large gains in yield-per-recruit could be realized by increasing the minimum harvest size.

Similarly, during the 1991 annual meeting, ICCAT's SCRS found that the rate of fishing mortality for small bluefin, ages 2–5, has increased generally to levels occurring in the mid-1970's, prior to regulations. The rate for medium fish, ages 6–7, has also increased to levels similar to or higher than the pre-1982 level, and fishing mortality on large fish (ages 8+) has increased considerably because the catches are being removed from a declining biomass.

The abundance of fish aged 10 and older is expected to continue to decline given that the year classes composing this category were all fished heavily prior to the 1982 regulations. Fish aged 8+ have continued to decline since 1982, and have declined 90 percent from the 1970 level. The overall exploitable biomass has declined to between 10 and 23 percent of the 1970 level. The SCRS further noted that the pattern of increased fishing mortality on small fish has reduced the potential for increase of the stock.

Based on the report of the SCRS, ICCAT adopted several recommendations for additional measures to enhance recovery of the bluefin stock beginning with the 1992 fishing year. These measures included: (1) That the Contracting Parties institute effective measures to limit the quota for the 2-year period 1992–1993 to 4,788 mt, but not to exceed 2,660 mt in the first year; (2) that the 2-year quota be taken by the Contracting parties in the same proportions as previously agreed to for 1990; (3) that beginning with the 1992 catch, if a Contracting Party exceeds its annual or 2-year quota, then in the 2-year period or the year following reporting of that catch to ICCAT, the Contracting Party will compensate in total by reducing the quota of the domestic catch category responsible for the overage; (4) that the three Contracting Parties will prohibit the taking and landing of bluefin weighing less than 30 kg, or in the alternative, having a fork length less than 115 cm, with discretion to grant tolerances of no more than 8 percent by weight of the total bluefin catch on a national basis; and (5) that the Contracting Parties institute measures to preclude economic gain to fishermen from landing bluefin less than 30 kg, or in the alternative, 115 cm. As a member of ICCAT, the United

States is obligated to adopt domestic regulations to comply with these recommendations. During December 1991 and January 1992, NMFS held scoping meetings to inform the public and initiate discussion of possible ways to implement the ICCAT recommendations. All sectors of the fishery were represented at these meetings.

NMFS received numerous written comments and input from the scoping meetings that suggested various proposals, some of which were adopted in the preferred alternative and others that will be considered for future rulemaking. NMFS considered all comments received during the scoping process while formulating this proposed rule. Further discussion can be found in the Environmental Assessment (see **ADDRESSES**).

Proposed Management Measures

The preferred alternative would implement the ICCAT recommendations as follows: (1) Reduce the total U.S. quota allocation by 10 percent for the 2-year period 1992 and 1993; (2) spread the reduction equally over the years 1992 and 1993, except for categories of fisheries that have begun fishing already in 1992; (3) apply the annual harvest amount among the categories based on the average landings of each category during the period 1983 to 1990; (4) reduce the allowable catch of bluefin less than 115 cm (45 inches) to no more than 8 percent of the annual U.S. allocation; (5) prohibit sale of bluefin less than 196 cm (77 inches); (6) implement area subquotas and differential bag limits in the Angling category for bluefin less than 115 cm (45 inches); (7) prohibit retention of young school bluefin (less than 66 cm 26 inches); (8) preclude vessels permitted for other categories from fishing in the Angling category and Angling category vessels from fishing in other categories; (9) implement a mechanism to subtract quota overages from the appropriate category in following years if the United States exceeds its allocation; (10) eliminate the adjustment to multiple catches per day in the General category; and (11) make other technical changes to enhance administration and enforcement.

Allocations

At the present time, the U.S. quota for a 2-year period equals 2,774 mt. The amount required to be subtracted for ICCAT compliance is 10 percent of 2,774 mt, or 277.4 mt. Thus, the U.S. 2-year quota for the period 1992 to 1993 becomes 2,496.6 mt. Because the reduction is applied over a 2-year period, a decision must be made regarding how to distribute it over the years. NMFS proposes to divide the reduction evenly over the 2-year period, with the exception of the Incidental category; the fishery in that category has already begun and has taken most of its 1992 quota. This category would absorb its full 2-year reduction in 1993.

A more difficult decision concerns the distribution of the available harvest amount among the participant-groups, keeping in view the mandates of ICCAT, the ATCA, and the effect such decisions will have on the depleted status of the resource, the resource users, and the economy in general. NMFS believes the mechanism of partitioning the quota allocations to match broadly defined user groups is basically sound and should be continued. However, a persistent problem exists in management of the Angling category. This category has exceeded its quota in past years by an average of approximately 200 mt per year over the period 1983 to 1990. Contributing to the problem is the difficulty of real-time quota monitoring of this wide-spread sector. The new ICCAT size limit will further exacerbate the problem, due to the reduction in the allowable harvest of small bluefin (less than 115 cm) and the need to monitor this quota to comply with the ICCAT measure. NMFS intends to improve monitoring in 1992 to enable more accurate prediction of the closure date. If further adjustments are not made, however, closure is likely to take place 2 to 4 weeks after the fishery begins. Such a closure would have serious economic and social consequences.

Action was taken recently to slow the catch rates in this fishery and lengthen the season slightly by reducing the daily catch limits in the Angling category (March 12, 1992, 57 FR 8728). Although many in the industry perceive the action as drastic, in fact, analysis shows that had these limits been imposed in previous years and all things remained equal, catches would have been reduced by a small amount, less than 10 percent, which is not enough to account for overages as high as 400 percent.

During the public hearings for the regulations to reduce the daily catch limit, charter/party boat fishermen asserted that, at a certain point, customers would not find it worthwhile to fish under reduced catch limits. To the extent that other species are not available as a substitute, financial losses could occur because customers are motivated to participate by their expectation of catching fish. By limiting this expectation at the outset by reduced daily limits, the customer's perception of the value of the fishing trip is diminished and the customer may choose not to participate. Given that severe reductions in the daily limits are needed to comply with the quota, and that the effects of the first reduction will not yet be known, NMFS believes that further reductions in the daily limits for party and charter vessels are not the best option at this time. However, since there were suggestions at the scoping meetings for differential bag limits for party/charter and private boat anglers, and NMFS data indicate that this could result either in lengthening the season, or at least in avoiding early closures in the fishery for bluefin less than 115 cm, NMFS proposes that only one fish less than 115 cm may be retained per vessel, other than party or charter vessel, per day.

Severe losses occur when the fishery is closed prematurely, especially during the season of good weather when people are interested in fishing. Premature closures affect anglers who are forced to choose either a lower valued activity or forgo participation in any activity. Any reduction in the length of the bluefin season has a negative impact on charter/party boat vessels, which lose revenues because they have a limited season to begin with, and because opportunities for these vessels to target other species may be limited. Unlike most other participants in the bluefin fishery, the value of the charter and party boat industry to participants is associated with participating in the activity, not with selling the fish. These are additional reasons for proposing the differential bag limits.

Therefore, NMFS believes it is appropriate to consider a preferred alternative that would contribute to preserving the length of the season. One of the proposals received during a scoping meeting was to distribute the amount available for harvest among the participant groups according to actual average landings. This can be accomplished by distributing the available harvest to user groups according to average performance levels during the period 1983 to 1990 (only preliminary 1991 data are available). This would allow the Angling category season for fish 115 cm and larger to remain open, even after the season for bluefin less than 115 cm is closed, while ensuring the quotas for the other categories are large enough to provide similar average annual revenues.

The rationale for this alternative is that the quota is based on the current conditions in each sector of the industry, rather than the set of conditions that existed in 1983. This approach follows the same analysis used in 1983; that is,

after the scientific objectives were met, catch levels, capacities, and levels of economic activity were assessed and allocations made accordingly wherever possible. For instance, in 1982, the Angling quota was set at 99 mt based on an approximation of the 5-year average catch of 105 mt (see proposed rule, April 12, 1982, 47 FR 17086).

This alternative conforms with all of the objectives agreed to by the United States in 1982 to guide the development of Atlantic bluefin tuna regulations, and most particularly enhances numbers (3), "to minimize economic displacement and preserve traditional fisheries", and (4), "to maximize the use of the available resource and spread the opportunity among as many users as possible."

This alternative recognizes the value of the opportunity to use the resource in addition to producing commercial revenue, including the economic activity generated from the effect that direct expenditures associated with fishing have on regional economies and employment. These direct expenditures include expenditures for food, bait, fuel, tackle, trip fares, tournament fees, marinas, etc. The "rippling effect" these expenditures generate is important to industries supplying the Angling category of the fluefin fishery and is sustained by preserving the traditional length of the season. Preservation of a full season of this activity may be as important to some local economies and employment as the actual tonnage of fish landed. Unfortunately, there are no data available to quantify this value; however, the preferred alternative is expected to produce these positive benefits.

NMFS scientists have pointed out that the long-term potential yield for western Atlantic bluefin could be greater than 10,000 mt, versus the recent allowable yield of 2,660 mt. Realization of the long-term potential yield level, through considered management of the bluefin fisheries, could result in a 4- to 5-fold gain in economic benefit compared to that which is experienced now. At the same time, realization of the long-term potential should considerably lower the risks of future loss due to further stock depletion. The approach NMFS has chosen has potential for reducing fishing mortality rates on all age classes of bluefin, thus providing a greater rebuilding potential for the stock. Because recent fishing mortality rates for medium and large bluefin have been near record highs, the potential gains from the present management program to the adult stock have likely been cropped before they could be realized. Reducing the fishing mortality rate on medium and large bluefin, as well as further actions to protect small fish, will allow for increases in the spawning potential of the stock. Thus, of those options immediately available, these proposed allocations of quota provide the best chances for enhancement of the recovery potential of the stock with minimal economic disruption.

A potential negative impact of this alternative would be a premature closure of the General category. Early closures negatively affect the General category for many of the same reasons as in the Angling category, because a portion of the participation there is for the fishing experience, which is separate from commercial-sale revenue. Managing this category to preserve the full length of season has long been a tenet of the regulations and was the sole reason for a rulemaking in 1984 when the category was prematurely closed in 1983 (see proposed rule at 49 FR 18574, May 1, 1984).

However, it is reasonable to assume premature closure is less probable, than in the Angling category, because the allocation reflects the average performance in the fishery from 1983 through 1990. To help ensure against early closure, the preferred alternative would eliminate the late-season adjustment from one to multiple bluefin per day to slow the late-season catch rate. Additional insurance against early closure is provided by the reserve amount of 85 mt. If the General category experiences a vigorous fishery, some of this amount could be allocated to that category.

The Purse Seine category also could experience a negative impact if the reserve is not distributed among the giant categories in proportion to their landings in 1983–1990. The quota under the preferred option, before any distribution of the reserve, would be 319 mt. This is 28 mt less than under a 10-percent reduction from existing quotas, but 83 mt more than this category took in 1991. If the reserve is distributed to the giant categories in proportion to 1983–1990 landings, the Purse Seine category would get 3 mt more than under a 10-percent reduction from the 1991 quota.

Another alternative considered but rejected would allocate the remaining U.S. quota among categories based on the subquotas established in 1983. NMFS believes that the cumulative effect of measures to solve existing problems in the Angling category and the new ICCAT measures would have a disproportionately severe impact on one category—perhaps even eliminate altogether the viability of the charter, party and private boat bluefin industry and its associated activities.

Implementation of Size Restrictions

The ICCAT recommendation provides that the catch of bluefin less than 115 cm may be limited to 8 percent of a nation's harvest. Because of the potential for serious economic and social disruption if no tolerance were allowed, the United States has chosen to implement this option. If the preferred alternative is adopted and the quota reduction amount distributed equally over the 2 years (with some exceptions), the allocation of bluefin less than 115 cm would equal 100 mt. The catch of fish this size essentially occurs only within the Angling category. An incidental-take option historically has been provided to the Purse Seine category, but has not been used; purse seine vessels harvest the available amount in giant bluefin instead. Therefore, allocating the entire amount to the Angling category and prohibiting the incidental take by pursue seiners is expected to have no impact on the purse seine sector, since it eliminates an option rather than a practice. This option is not expected to affect any other categories besides the Angling category because the other directed categories must, by regulation, target giants and the incidental category has, in recent years, harvested large fish because of the location of their fisheries and the economic return from larger fish.

A long-standing ICCAT provision prohibits the harvest of bluefin less than 6.4 kg (26 inches) but allows nations to harvest up to 15 percent of their annual allocation for fish of that size. Because U.S. fishermen harvest most of these fish with rod and reel, and, therefore, the fish may be released live, NMFS sees no reason for a bycatch allowance and proposes to prohibit retention of bluefin less than 6.4 kg (26 inches) in accordance with the ICCAT recommendation.

No Economic Gain Provision

ICCAT stipulates that no economic gain be derived from the catch of bluefin less than 115 cm. The preferred alternative would implement this by prohibiting the sale of this size bluefin, as well as the sale of all bluefin less than giant (196 cm).

The benefits of this provision would be to extend the Angling category season, discourage the development of a commercial fishery for small fish (which would result in a lower-value product), and increase the yield-per-recruit (see the Regulatory Impact Review for

comparisons of prices paid per pound based on size of fish).

The no-sale provision for all fish less than giant (196 cm) will have an adverse revenue impact on those who otherwise would have sold the fish. Compared to a 10-percent reduction from 1991 quotas, revenues would be $260,000 less. Counterbalancing this adverse revenue impact would likely be an extended season for those who wish to fish despite the loss of the option to sell. The extended season will be economically advantageous to the Angling support sectors—charter boats, marinas, bait shops, etc. The extended season may also result in greater angler satisfaction for the anglers who have more opportunity to attempt to catch bluefin and would not have sold the bluefin anyway. The length of the extension of the season in the face of a no-sale provision is not quantifiable and depends on how anglers react to no-sale.

Area Subquotas

Area set-asides or subquotas are proposed to be continued in both the General and Incidental longline categories to mitigate against a particular geographic region's losing the opportunity to harvest fish due to fluctuations in migratory patterns and resource availability. Area subquotas are proposed for the Angling category because the limited amount available for bluefin less than 115 cm is expected to create a problem in keeping the season open in the Angling category for fish that size. Small bluefin usually appear off the Virginia Capes first and, depending on abundance and weather, a substantial portion of the quota for bluefin less than 115 cm or even the entire amount could be harvested from this one area and thereby precluded fishing farther north. To prevent this, the proposed rule would establish an area subquota for fishermen landing in Delaware and states south, and another subquota for fishermen landing in New Jersey and states north. These subquotas are based on the historical pattern of landings for those areas during the period 1988 to 1990.

Prohibiting Fishing From Angling and Other Categories During the Same Season

Some fishermen harvest from both the General and the Angling category quotas in a single season. NMFS believes that, given the limited quota available, vessels should be limited to one quota category per season to spread the opportunity to use the resource among as many participants as possible. This is the intent of the May 15 cut-off date that prevents changes in permit categories and, hence, fishing from two of the permitted quota categories in the same season. The preferred alternative would extend this provision, which already exists for the other categories, to the Angling category.

Subtracting Overages

Subtracting overages from a particular subquota category is an ICCAT requirement. Many of the provisions described in this document are designed to regulate fisheries and prevent overages from occurring, making "subtracting" unnecessary. Nevertheless, in the event the United States exceeds its annual allocation, these regulations would provide that overages be subtracted from the responsible subquota category in the following year.

Other Measures

Some proposed measures are administrative or technical modifications that should have negligible impact. Section 285.20 would be revised to clarify that information from previous years' catch may be use of the sections revised that specify a tonnage amount, U.S. tons would be converted to metric tons as part of an ongoing process to provide consistency with the statistics cited by scientists and ICCAT, which are in metric. Section 285.22 would be amended to clarify that harvests resulting from scientific experiments authorized under § 285.1 may be attributed to the inseason adjustment (reserve) quota. Section 285.25 would be revised to require that purse seine vessels carry a NMFS-approved observer if selected and notified in writing by the Regional Director. The purpose of the observer requirement is to collect scientific data on the resource. The size class for school bluefin contained in the table in § 285.26 would be divided into two size classes, "school" and "large school", to distinguish between bluefin less than 115 cm and those between 115 cm and 145 cm. Sections 285.20, 285.21, 285.22 and 285.31 would be revised to incorporate these new size classes. Sections 285.29, 285.30 and 285.31 would be revised by removing reference to size classes altogether, or to indicate size classes that would be prohibited from commercial sale or retention. Section 285.31 would be revised to clarify how to release unharmed fish that will not be retained, and to prohibit refusal to provide information necessary to monitor the stock to NMFS or its agents.

Additonal Measures Under Consideration

Several management measures or suggested changes that were brought up during the scooping process are being considered or evaluated by NMFS. Numerous complaints have been received concerning the "heads on" landing requirement in the existing regulations. NMFS believes this should be evaluated and will work with the industry to make a final determination on this requirement. NMFA invites comments on this issue.

Certificates of origin for all bluefin imported or exported are currently under consideration by ICCAT countries. There were numerous comments suggesting permitting vessels in the Angling category. There were requests for observer coverage on vessels in all categories. These would aid data collection and monitoring efforts but would involve Paperwork Reduction Act requirements and will be addressed in future rulemaking. Several recommendations concerning the incidental longline fishery in the Gulf of Mexico also will be considered in future rulemaking.

Classification

This proposed rule is published under the authority of the ATCA, 16 U.S.C. 971 *et seq.* The Assistant Administrator for Fisheries, NOAA (Assistant Administrator), has determined that this proposed rule is necessary to implement the recommendations of ICCAT and is necessary for management of the Atlantic bluefin tuna fishery.

An environmental assessment (EA), prepared by NMFS, concludes that there will be no significant impact on the human environment as a result of this action. A copy of the EA is available (see **ADDRESSES**).

The Assistant Administrator has determined, based on the Regulatory Impact Review (RIR) prepared for this rule, that this is not a "major" rule requiring a Regulatory Impact Analysis under E.O. 12291. The proposed action will not have a cumulative effect on the economy of $100 million or more, nor will it result in a major increase in costs to consumers, industries, government agencies, or geographical regions. No significant adverse effects on competition, employment, investment, productivity, innovation, or competitiveness of U.S.-based enterprises are anticipated.

The RIR concludes that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities

under the Regulatory Flexibility Act. According to the RIR, the reduction in overall bluefish catch necessary to comply with the ICCAT recommendations is expected to result in aggregate annual net revenue losses for the fleet amounting to an estimated $2.2 million (see RIR, section V.B.). Approximately 52 out of thousands of vessels may experience a significant (>25 percent of income) loss of income as a result of the one-category-per-season measure in § 285.21 proposed by this rule (RIR, section V.C.). The amount of the loss will depend on the success of these fishermen in the category they choose, or in targeting alternative species, and the costs associated with these alternatives. You may obtain a copy of the RIR from NMFS (see ADDRESSES).

The Assistant Administrator has determined that this proposed rule will be implemented in a manner that is consistent to the maximum extent practicable with the approved coastal zone management programs of the Atlantic, Gulf of Mexico, and Caribbean states that have approved coastal zone management programs. These determinations have been submitted for review by the responsible state agencies under section 307 of the Coastal Zone Management Act.

This proposed rule does not contain any new collection-of-information requirements subject to the Paperwork Reduction Act. It repeats requirements that were approved by the Office of Management and Budget under OMB control numbers 0648–0202 and 0648–0239. They are repeated because changes in the definitions for size classes and the change in size for sale required changing or deleting several words in existing text. Public reporting burden for these collections of information is estimated to average 15 minutes per response for vessel permit application and 2 minutes per response for dealer reporting. These estimates include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding these burden estimates or any other aspects of these collections of information, including suggestions for reducing the burden, to NMFS (see ADDRESSES) and the Office of Information and Regulatory Affairs, OMB, Washington, DC 20503 (Attention NOAA Desk Officer).

NMFS is consulting under section 7 of the Endangered Species Act concerning the potential impact of this fishery and of the proposed management measures on endangered and threatened species.

This proposed rule does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under E.O. 12612.

List of Subjects in 50 CFR Part 285

Fisheries, Penalties, Reporting and recordkeeping requirements, Treaties.

Dated: April 22, 1992.

Michael F. Tillman,

Acting Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set forth in the preamble, 50 CFR part 285 is proposed to be amended as follows:

PART 285—ATLANTIC TUNA FISHERIES

1. The authority citation for part 285 continues to read as follows:

Authority: 16 U.S.C. 971 *et seq.*

2. In § 285.2, new definitions for "charter boat", "party boat", and "private boat" are added in alphabetical order, and the definition of "Regional Director" is revised to read as follows:

§ 285.2 Definitions.

* * * * *

Charter boat means a vessel whose operator is licensed by the U.S. Coast Guard to carry six or fewer paying passengers and whose passengers fish for a fee.

* * * * *

Party boat means a vessel whose operator is licensed by the U.S. Coast Guard to carry seven or more paying passengers and whose passengers fish for a fee.

* * * * *

Private boat means any vessel fishing in the Angling category other than charter or party boats.

* * * * *

Regional Director means the Director of the Office of Fisheries Conservation and Management, 1335 East-West Highway, Silver Spring, MD 20910.

* * * * *

3. In § 285.20, paragraph (a)(1)(i) is removed, paragraphs (a)(1)(ii) through (a)(1)(iv) are redesignated paragraphs (a)(1)(i) through (a)(1)(iii), respectively; and newly redesignated paragraphs (a)(1)(i) and (a)(1)(ii) and paragraphs (b)(1) and (b)(3) are revised to read as follows:

§ 285.20 Fishing seasons.

(a) * * *

(1) * * *

(i) For anglers fishing for school, large school, and medium Atlantic bluefin tuna under the quota specified in § 285.22(d);

(ii) For vessels permitted in the Incidental Catch category fishing under the quota specified in § 285.22(e); and

* * * * *

(b) * * *

(1) The Assistant Administrator will monitor catch and landing statistics, including catch and landing statistics from previous years and projections based on those statistics, of Atlantic bluefin tuna by vessels other than those permitted in the Purse Seine category. On the basis of these statistics, the Assistant Administrator will project a date when the catch of Atlantic bluefin tuna will equal any quota under § 285.22, and will publish a notice in the **Federal Register** stating that fishing for or retaining Atlantic bluefin tuna under that quota must cease on that date at a specific hour.

* * * * *

(3) A vessel permitted in the Purse Seine category may fish under the quota specified in § 285.22(c) only until the allocation assigned or transferred under § 285.25(d) to that vessel is reached. Upon reaching its individual vessel allocation of Atlantic bluefine tuna, a vessel will be deemed to have been given notice that the fishery for such tuna is closed to that vessel.

* * * * *

4. Section 285.21 is amended by revising paragraphs (a) and (b) to read as follows:

§ 285.21 Vessel permits.

(a) *Permit requirements.* Each vessel that fishes for or takes Atlantic bluefin tuna, except vessels being used by anglers fishing for school, large school, or medium Atlantic bluefin under § 285.24(c), must have an appropriate permit issued under this section.

(b) *Categories of permits.* The Regional Director will issue a permit to each vessel for only one of the following categories: General (handgear), Harpoon Boat, Purse Seine, or Incidental Catch. A permitted vessel is entitled to fish for Atlantic bluefin tuna only under the quota for the category in which it is permitted, and must use gear appropriate to that category. Anglers may fish for school, large school and medium Atlantic bluefin tuna only from a vessel that is not permitted in any other category. Anglers are subject to provisions of this subpart applicable to angling. The Regional Director will issue permits to catch and retain Atlantic bluefin tuna under § 285.22(c) only to current owners of those purse seine vessels, or their replacements, that were

granted allocations under this subpart and landed Atlantic bluefin tuna in the fishery for Atlantic bluefin tuna during the period 1980 through 1982. The Regional Director will not issue a permit to take Atlantic bluefin tuna under this subpart to any vessel that was replaced with another vessel and retired from the purse seine fishery during the period 1980 through 1982, unless that vessel is replacing another vessel being retired from the fishery.

* * * * *

5. Section 285.22 is revised to read as follows:

§ 285.22 Quotas.

The total annual amount of Atlantic bluefin tuna that may be caught and retained by persons and vessels subject to U.S. jurisdiction in the regulatory area is subdivided as follows:

(a) *General.* The total amount of giant Atlantic bluefin tuna that may be caught and retained in the regulatory area by vessels permitted in the General category under § 285.21(b) is 410 mt. If the Assistant Administrator determines (based on dealer reports, availability of giant Atlantic bluefin tuna on the fishing grounds, and any other relevant information), that variations in seasonal distribution, abundance, or migration patterns of Atlantic bluefin tuna, and the catch rate, may prevent fishermen in an identified area from harvesting their share of the quota, the Assistant Administrator may set aside an allocation for such area. The amount of any allocation will not exceed the greater of 45 mt or the maximum reported landings in the identified area in any of the preceding 3 years. The Assistant Administrator will publish a notice of any allocation and its basis in the **Federal Register.** The daily catch limit for the identified area will be set at one giant Atlantic bluefin tuna per day per vessel.

(b) *Harpoon Boat.* The total amount of giant Atlantic bluefin tuna that may be caught and retained in the regulatory area by vessels permitted in Harpoon Boat category under § 285.21(b) is 54 mt.

(c) *Purse Seine.* The total amount of giant Atlantic bluefin tuna that may be caught and retained in the regulatory area by vessels permitted in the Purse Seine category under § 285.21(b) is 319 mt.

(d) *Angling.* The total amount of school, large school, and medium Atlantic bluefin tuna that may be caught and retained in the regulatory area by anglers is 271 mt. No more than 100 mt of this quota may be school Atlantic bluefin tuna. This quota is further subdivided as follows:

(1) 47 mt of school Atlantic bluefin tuna may be landed in Delaware and states south;

(2) 53 mt of school Atlantic bluefin tuna may be landed in New Jersey and states north.

(e) *Incidental.* The total amount of Atlantic bluefin tuna that may be caught and retained in the regulatory area by vessels permitted in the Incidental Catch category under § 285.21(b) is 137 mt. This quota is further subdivided as follows:

(1) In 1992, 132 mt for longline vessels. No more than 104 mt may be taken in the area south of 36°00′ N. latitude.

(2) In years after 1992, 78 mt for longline vessels. No more than 61 mt may be taken in the area south of 36°00′ N. latitude.

(3) 5 mt for vessels fishing for species of fish other than tuna.

(f) *Inseason adjustment amount.* The total amount of Atlantic bluefin tuna that will be held in reserve for inseason adjustments is 85 mt. The Assistant Administrator may allocate any portion (from zero to 100 percent) of this amount to any category or categories of the fishery, including research activities authorized under § 285.1(c). The Assistant Administrator will publish a notice of a location of any inseason adjustment amount in the **Federal Register** before such allocation is to become effective. Before making any such allocation, the Assistant Administrator will consider the following factors:

(1) The usefulness of information obtained from catches of the particular category of the fishery for biological sampling and monitoring the status of the stock;

(2) The catches of the particular gear segment to date and the likelihood of closure of that segment of the fishery if no allocation is made;

(3) The projected ability of the particular gear segment to harvest the additional amount of Atlantic bluefin tuna before the anticipated end of the fishing season; and

(4) The estimated amounts by which quotas established for other gear segments of the fishery might be exceeded.

(g) The catching or retention of school, large school or medium Atlantic bluefin tuna is prohibited except as allowed by paragraph (d) of this section.

(h) Beginning in 1993, if the Assistant Administrator determines, based on landing statistics and other available information, that harvests from persons and vessels subject to U.S. jurisdiction in the regulatory area have exceeded the total amount available, then the total amount available for the current fishing year will be the total amount available in the preceding year minus the amount of excess harvest. The excess harvest will be subtracted from the domestic category or categories in which the overage occurred. The Assistant Administrator will publish any amounts to be subtracted and the basis for the quota reductions in the **Federal Register.**

6. Section 285.23 is revised to read as follows:

§ 285.23 Incidental catch.

(a) *Herring, mackerel, and menhaden purse seine vessels and vessels using fixed gear other than longlines or traps (pounds, weirs, and gill-nets).* Subject to the quotas in § 285.22, any person operating a vessel fishing with these types of gear principally for species of fish other than tuna and possessing an Incidental Catch permit issued under § 285.21 may retain during any fishing trip, giant Atlantic bluefin tuna, provided that the total amount of Atlantic bluefin tuna taken does not exceed 2 percent, by weight, of all other fish aboard the vessel at the end of each fishing trip.

(b) *Traps.* Subject to the quotas in § 285.22, any person operating a vessel possessing an Incidental Catch permit issued under § 285.21 that catches Atlantic bluefin tuna incidentally while fishing with traps, may retain giant Atlantic bluefin tuna, provided that such tuna do not exceed 2 percent, by weight, of the total amount of all other species caught within the preceding 30-day period.

(c) *Longlines.* Subject to the quotas in § 285.22, any person operating a vessel using longline gear possessing an Incidental Catch permit issued under § 285.21 may retain or land giant Atlantic bluefin tuna as an incidental catch. The amount of Atlantic bluefin tuna retained or landed may not exceed:

(1) One fish per vessel per trip landed south of 36°00′ N. latitude, provided that at least 2,500 lbs (1,134 kg) of species other than Atlantic bluefin tuna are landed and offloaded from the same trip and are recorded on the dealer weighout as sold; and

(2) Two percent by weight of all other fish landed, offloaded and documented on the dealer weightout as sold at the end of each fishing trip, north of 36°00′ N. latitude.

(d) *Rod and reel.* Subject to the quotas in § 285.22, any person operating a vessel using rod and reel gear in the Gulf of Mexico and possessing an Incidental Catch permit issued under § 285.21 may catch and retain annually one giant Atlantic bluefin tuna as an incidental catch. The permit holder must

report to the nearest NMFS enforcement office within 24 hours of landing any giant bluefin, and must make the tuna available for inspection and attachment of a metal tag. No such Atlantic bluefin tuna may be sold or transferred to any persons for a commercial purpose.

(e) *Other gear.* Incidental harvest of Atlantic bluefin tuna by gear other than specified in § 285.22 or in this section is prohibited.

7. Section 285.24 is amended by revising paragraphs (a) and (c) to read as follows:

§ 285.24 Catch limits.

(a) From June 1, vessels permitted in the General category under § 285.21 may catch only one giant Atlantic bluefin tuna per day per vessel.

* * * * *

(c) *Angling category.* (1) Anglers may catch and retain each day no more than two Atlantic bluefin tuna, only one of which may be a medium and only one of which may be a school bluefin tuna. Anglers may not retain giant or young school Atlantic bluefin tuna.

(2) Party and charter boats may catch and retain each day the bag limit for anglers specified in paragraph (c)(1) of this section for each angler on board; provided, however, that no more than two medium bluefin tuna may be retained each day, regardless of the number of anglers on board.

(3) Private boats, with two or more anglers on board, may catch and retain each day the bag limit for anglers specified in paragraph (c)(1) of this section for the number of anglers on board; provided, however, that no more than two medium and one school bluefin tuna may be retained each day, regardless of the number of anglers on board.

8. Section 285.26 is amended by revising the table to read as follows:

§ 285.26 Size classes.

* * * * *

Size class	Total fork length	Pectoral fin fork length	Approx. round weight
Young school.	<26 in (<66 cm).	<19 in (<48 cm).	<14 lbs (<6.4 kg).
School	26 to <45 in (66 to <115 cm).	19 to <33 in (48 to <84 cm).	14 to <66 lbs (6.4 to <30 kg).
Large school.	45 to <57 in (114 to <145 cm).	33 to <42 in (84 to <107 cm).	66 lbs to <135 lbs (30 to <62 kg).
Medium	57 to <77 in (145 to <196 cm).	42 to <57 in (107 to <145 cm).	135 to <310 lbs (61 to <140 kg).
Giant	77 in or greater (196 cm).	57 in or greater (145 cm).	310 lbs or greater (140 kg).

9. Section 285.29 is amended by revising paragraph (a) to read as follows:

§ 285.29 Dealer recordkeeping and reporting.

* * * * *

(a) Must submit to the Regional Director a daily report on a reporting card provided by NMFS, within 24 hours of the purchase or receipt of each Atlantic bluefin tuna that was purchased from the person or vessel that harvested the fish. Said card must be postmarked within 24 hours of the purchase or receipt of each Atlantic bluefin tuna. Each reporting card must be signed by the vessel permit holder or vessel operator to verify the name of the vessel that landed the fish and must show the Atlantic bluefin tuna vessel permit number, metal tag number affixed to the fish by the dealer or assigned by an authorized officer, the date landed, the port where landed, the round or dressed weight, the fork length, gear used, and area where caught.

* * * * *

10. Section 285.30 is amended by revising paragraphs (c)(1) and (d) to read as follows:

§ 285.30 Metal tags.

* * * * *

(c) * * *

(1) A dealer or agent must affix a metal tag to each Atlantic bluefin tuna purchased or received immediately upon its offloading from a vessel. The metal tag must be affixed to the tuna between the fifth dorsal finlet and the keel.

* * * * *

(d) *Removal of tags.* A metal tag affixed to any Atlantic bluefin tuna must remain on the tuna until the tuna is either cut into portions or sold for export from the United States. If the tuna or tuna parts subsequently are packaged for transport for domestic commercial use or for export, the tag number must be written legibly and indelibly on the outside of any package or container. Tag numbers must be recorded on any document accompanying shipment of bluefin tuna for commercial use or export.

11. Section 285.31 is amended by revising paragraphs (a)(17), (a)(18), (a)(26), and (a)(28) and adding paragraphs (a)(34) through (a)(39) to read as follows:

§ 285.31 Prohibitions.

(a) * * *

(17) Fail to release immediately with a minimum of injury any Atlantic bluefin tuna that will not be retained;

(18) Fail to affix immediately to any Atlantic bluefin tuna, between the fifth dorsal finlet and the keel, an individually numbered metal tag when the tuna has been received or purchased by that person for a commercial purpose from any person or vessel having caught such tuna;

* * * * *

(26) Fish for or catch Atlantic bluefin tuna with longline gear except as provided in § 285.23(e);

* * * * *

(28) Fish for or catch school, large school or medium Atlantic bluefin tuna with gear other than hook and line, which is held by hand or rod and reel made for this purpose;

* * * * *

(34) Retain young school Atlantic bluefin tuna for any purpose;

(35) Sell, offer for sale, purchase, receive for a commercial purpose, trade or barter any Atlantic bluefin tuna other than a giant;

(36 Refuse to permit access of NMFS personnel to inspect any records relating to, or area of custody of, Atlantic bluefin tuna;

(37) Refuse to provide information requested by NMFS personnel or anyone collecting information for NMFS relating to the scientific monitoring or management of Atlantic bluefin tuna; or

(38) Retain or land any Atlantic bluefin tuna by gear other than specified in § 285.22 or 285.23.

(39) Retain or land any bluefin tuna less than 196 cm by any vessels permitted under §§ 285.21.

[FR Doc. 92-9782 Filed 4-23-92; 8:45 am]

BILLING CODE 3510-22-M

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50 CFR Parts 672 and 675

Groundfish of the Gulf of Alaska; and Groundfish of the Bering Sea and Aleutian Islands

AGENCY: National Oceanic and Atmospheric Administration, Commerce.

ACTION: Notice of availability of amendments to fishery management plans; request for comments.

SUMMARY: NMFS issues this notice that the North Pacific Fishery Management Council (Council) has submitted Amendment 19 to the Fishery Management Plan (FMP) for the

Groundfish Fishery of the Bering Sea and Aleutian Islands Area (BSAI) and Amendment 24 to the FMP for Groundfish of the Gulf of Alaska (GOA) for Secretarial review and is requesting comments from the public. Copies of the amendments may be obtained from the Council (see **ADDRESSES**).

DATES: Comments on the FMP amendments should be submitted on or before June 22, 1992.

ADDRESSES: Comments on the FMP amendments should be submitted to Steven Pennoyer, Director, Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802.

Copies of the amendments with the Environmental Assessment/Regulatory Impact Review/Initial Regulatory Flexibility Analyses are available from the North Pacific Fishery Management Council, P.O. Box 103136, Anchorage, AK 99510.

FOR FURTHER INFORMATION CONTACT: Susan Salveson, National Marine Fisheries Service, Alaska Region, 907-586-7228.

SUPPLEMENTARY INFORMATION: The Magnuson Fishery Conservation and Management Act (Magnuson Act) requires that each Regional Fishery Management Council submit any fishery management plan or plan amendment it prepares to the Secretary of Commerce (Secretary) for review and approval, disapproval, or partial disapproval. The Magnuson Act also requires that the Secretary, upon reviewing the plan or amendment, must immediately publish a notice that the plan or amendment is available for public review and comment. The Secretary will consider the public comments received during the comment period in determining whether to approve the plan or amendment.

The Secretary proposes regulations that would implement Amendment 19 to the FMP for the Groundfish Fishery of the BSAI and Amendment 24 to the FMP for Groundfish of the GOA. If approved, these regulations would implement the following amendment measures:

(1) For 1992, reduce the Pacific halibut prohibited species catch (PSC) limit established for BSAI trawl gear from 5,333 metric tons (mt) to 5,033 mt, but retain the primary halibut PSC limit at 4,400 mt;

(2) For 1992, establish a 750 mt Pacific halibut bycatch mortality limit for BSAI fixed gear; and

(3) Establish FMP authority to develop and implement regulatory amendments that allow for time/area closures to reduce prohibited species bycatch rates.

In addition to the above FMP amendments, the following amendments to current implementing regulations are proposed:

(1) Revise BSAI fishery definitions for purposes of monitoring fishery specific bycatch allowances and assigning vessels to fisheries for purposes of the vessel incentive program;

(2) Revise the management of BSAI trawl fishery categories that are eligible to receive prohibited species bycatch allowances;

(3) Expand the vessel incentive program to address halibut bycatch rates in all trawl fisheries;

(4) Delay the season opening date of the BSAI and GOA groundfish trawl fisheries to January 20 of each fishing year to reduce salmon and halibut bycatch rates;

(5) Further delay the season opening date of the GOA trawl rockfish fishery to the Monday closest to July 1 to reduce halibut and chinook salmon bycatch rates; and

(6) Change directed fishing standards to further limit halibut bycatch associated with bottom trawl fisheries.

Regulations proposed by the Council and based on this amendment are scheduled to be published within 15 days of this notice.

List of Subjects in 50 CFR Parts 672 and 675

Fisheries, Reporting and recordkeeping requirements.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: April 22, 1992.

David S. Crestin,

Acting Director, Officer of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 92-9736 Filed 4-22-92; 2:23 pm]

BILLING CODE 3510-22-M

Notices

Federal Register
Vol. 57, No. 82
Tuesday, April 28, 1992

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Soil Conservation Service

Delmar Community Development RC&D Measure, Delaware

AGENCY: Soil Conservation Service, USDA.

ACTION: Notice of a finding of no significant impact.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Guidelines (40 CFR part 1500); and the Soil Conservation Service Guidelines (7 CFR part 650); the Soil Conservation Service, U.S. Department of Agriculture gives notice that an environmental impact statement is not being prepared for the Delmar Community Development RC&D Measure, Sussex County, Delaware.

FOR FURTHER INFORMATION CONTACT: Mr. Timothy Garrahan, District Conservationist, Soil Conservation Service, 408 N. DuPont Highway, Georgetown, Delaware 19947, telephone (302) 856-7378.

SUPPLEMENTARY INFORMATION: The environmental assessment of this federally assisted action indicates that the project will not cause significant local, regional, or national impacts on the environment. As a result of these findings, Timothy Garrahan, District Conservationist, has determined that an environmental impact statement is not needed for this project.

The measure concerns a plan to: (1) Develop and follow an intensive tree management plan for all of the trees in public ownership in the Town of Delmar, (2) increase the general usage of State Street Park by replacing deteriorating playground equipment, (3) resurface a tennis court, (4) install a 800-foot waterway with a 800-foot tile drain in the bottom to correct a drainage problem, and (5) plant 250 trees at strategic locations throughout the community.

The installation of this project will increase the quality of life in this small community.

The Notice of Finding of No Significant Impact (FONSI) has been forwarded to the Environmental Protection Agency and to various federal, state, and local agencies and interested parties. A limited number of copies of the FONSI are available to fill single copy requests at the above address. Basic data developed during the environmental evaluation are on file and may be reviewed by contacting Mr. Timothy Garrahan.

No administrative action on implementation of the proposal will be taken until 30 days after the date of this publication in the **Federal Register.**

(Catalog of Federal Domestic Assistance Under No. 10.901, Resource Conservation and Development, and is subject to the provision of Executive Order 12372 which requires intergovernmental consultation with state and local officials.)

Dated: April 16, 1992.

Elesa K. Cottrell,

State Conservationist.

[FR Doc. 92-9774 Filed 4-27-92; 8:45 am]

BILLING CODE 3410-16-M

Delaware State College Aquaculture RC&D Measure, Delaware

AGENCY: Soil Conservation Service, USDA.

ACTION: Notice of a finding of no significant impact.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Guidelines (40 CFR part 1500); and the Soil Conservation Service Guidelines (7 CFR part 650); the Soil Conservation Service, U.S. Department of Agriculture gives notice that an environmental impact statement in not being prepared for the Delmar Community Development RC&D Measure, Sussex County, Delaware.

FOR FURTHER INFORMATION CONTACT: Mr. Ralph Timmons, District Conservationist, Soil Conservation Service, 3500 S. DuPont Highway, Dover, Delaware 19901, telephone (302) 697-9540.

SUPPLEMENTARY INFORMATION: The environmental assessment of this federally assisted action indicates that the project will not cause significant local, regional, or national impacts on the environment. As a result of these findings, Ralph Timmons, District Conservationist, has determined that an environmental impact statement is not needed for this project.

The measure concerns a plan to: (1) Build a series of interconnecting research ponds (2) exchange soil material to remove the course materials and organic soil from the proposed pond sites to an adjacent athletic field that is under development, and transfer finer soil material (clay) from the athletic field to the pond area, (3) drill two water wells to supply water to the ponds, (4) install a 4-12 inch pipe system to exchange water between ponds, (5) install a series of monitoring wells to determine the potential impact on the ground water, (6) apply the appropriate amount of lime, fertilizer, and mulch to all disturbed areas, and (7) erect a fence around the site to separate the athletic field from the aquaculture research complex.

The installation of this project will (1) promote aquaculture which will supplement the income of several hundred farm producers throughout the state, (2) help to develop a new industry in the state, and (3) increase the job opportunities for students from Delaware State College's Department of Agriculture and Natural Resources.

The Notice of Finding of No Significant Impact (FONSI) has been forwarded to the Environmental Protection Agency and to various federal, state, and local agencies and interested parties. A limited number of copies of the FONSI are available to fill single copy requests at the above address. Basic data developed during the environmental evaluation are on file and may be reviewed by contacting Mr. Ralph Timmons.

No administrative action on implementation of the proposal will be taken until 30 days after the date of this publication in the **Federal Register.**

(Catalog of Federal Domestic Assistance Under No. 10.901, Resource Conservation and Development, and is subject to the provision of Executive Order 12372 which requires intergovernmental consultation with state and local officials.)

Dated: April 16, 1992.

Blesa K. Cottrell,

State Conservationist.

[FR Doc. 92-9775 Filed 4-27-92; 8:45 am]

BILLING CODE 3410-16-M

DEPARTMENT OF COMMERCE

Agency Form Under Review by the Office of Management and Budget

DOC has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: Bureau of the Census.

Title: Survey of Income and Program Participation – 1991 Panel Wave 6.

Form Number(s): SIPP-11600 Questionnaire, SIPP-11605(L) Introductory Letter.

Agency Approval Number: 0607-0702.

Type of Request: Revision of a currently approved collection.

Burden: 44,100 hours.

Number of Respondents: 29,400.

Avg Hours Per Response: 30 minutes.

Needs and Uses: The Survey of Income and Program Participation (SIPP) provides information concerning the distribution of income received directly as money or indirectly as in-kind benefits and the effect of tax and transfer programs on this distribution. The survey is molded around a central core of labor force and income questions that are periodically supplemented with additional questions, referred to as topical modules, designed to answer specific needs. The topical modules for the 1991 panel Wave 6 duplicate those of the 1992 Panel Wave 3 (being submitted to OMB concurrently) and are referred to collectively as the "Extended Measures of Well-Being" module. The individual components are the following: (1) Consumer Durables, (2) Living Conditions, (3) Basic Needs, (4) Expenditures, and (5) Minimum Income. Wave 6 interviews will be conducted from October 1992 through January 1993.

Affected Public: Individuals or households.

Frequency: Once during the panel.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Maria Gonzalez, (202) 395-7313.

Copies of the above information collection proposal can be obtained by calling or writing Edward Michals, DOC Forms Clearance Officer, (202) 377-3271, Department of Commerce, room 5312, 14th and Constitution Avenue, NW., Washington, DC 20230.

Written comments and recommendations for the proposed information collection should be sent to Maria Gonzalez, OMB Desk Officer, room 3208, New Executive Office Building, Washington, DC 20503.

Dated: April 22, 1992.

Edward Michals,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 92-9805 Filed 4-27-92; 8:45 am]

BILLING CODE 3510-07-F

Agency Form Under Review by the Office of Management and Budget

DOC has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: Bureau of the Census.

Title: Survey of Income and Program Participation – 1992 Panel Wave 3.

Form Number(s): SIPP-12300 Questionnaire, SIPP-12305 Introductory Letter, and SIPP-12304(A-D) Flashcard Pamphlet.

Agency Approval Number: 0607-0723.

Type of Request: Revision of a currently approved collection.

Burden: 63,000 hours.

Number of Respondents: 42,000.

Avg Hours Per Response: 30 minutes.

Needs and Uses: The Survey of Income and Program Participation (SIPP) provides information concerning the distribution of income received directly as money or indirectly as in-kind benefits and the effect of tax and transfer programs on this distribution. The survey is molded around a central core of labor force and income questions that are periodically supplemented with additional questions, referred to as topical modules, designed to answer specific needs. The topical modules for the 1992 panel Wave 3 duplicate those of the 1991 Panel Wave 6 (being submitted to OMB concurrently) and are referred to collectively as the "Extended Measures of Well-Being" module. The individual components are the following: (1) Consumer Durables, (2) Living Conditions, (3) Basic Needs, (4) Expenditures, and (5) Minimum Income. Wave 3 interviews will be conducted from October 1992 through January 1993.

Affected Public: Individuals or households.

Frequency: Once during the panel.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Maria Gonzalez, (202) 395-7313.

Copies of the above information collection proposal can be obtained by calling or writing Edward Michals, DOC Forms Clearance Officer, (202) 377-3271, Department of Commerce, room 5312, 14th and Constitution Avenue, NW., Washington, DC 20230.

Written comments and recommendations for the proposed information collection should be sent to Maria Gonzalez, OMB Desk Officer, room 3208, New Executive Office Building, Washington, DC 20503.

Dated: April 22, 1992.

Edward Michals,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 92-9804 Filed 4-27-92; 8:45 am]

BILLING CODE 3510-07-F

Agency Form Under Review by the Office of Management and Budget

DOC has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: Bureau of the Census.

Title: Construction Improvements and Maintenance and Repairs Supplement.

Form Number(s): EIA-87IG.

Agency Approval Number: None.

Type of Request: New collection.

Burden: 1,050 hours.

Number of Respondents: 6,300.

Avg Hours Per Response: 10 minutes.

Needs and Uses: The Census Bureau is sponsoring these supplemental questions on construction improvements and maintenance and repair expenditures to nonresidential buildings, which will appear in an upcoming Department of Energy (DOE) survey called the Commercial Buildings Energy Consumption Survey (CBECS). Within DOE, this survey is conducted every three years by the Energy Information Administration (EIA). These questions will measure a component of total construction activity which is not accurately reflected in other surveys; only very large improvement projects are included in existing surveys. Without data on improvements, maintenance, and repairs, estimates of the value of construction put in place would be understated. The EIA collected these data for the Census Bureau in its 1986 and 1989 CBECS. The results from the 1989 survey indicate that existing surveys missed nearly $15 billion of improvements expenditures and another $35 billion spent for maintenance and repairs.

Affected Public: State or local governments, Businesses or other for-profit organizations, Federal agencies or employees, Non-profit institutions, Small businesses or organizations.

Frequency: Once every three years.

Respondent's Obligation: Voluntary.
OMB Desk Officer: Maria Gonzalez, (202) 395-7313.

Copies of the above information collection proposal can be obtained by calling or writing Edward Michals, DOC Forms Clearance Officer, (202) 377-3271, Department of Commerce, room 5312, 14th and Constitution Avenue, NW., Washington, DC 20230.

Written comments and recommendations for the proposed information collection should be sent to Maria Gonzalez, OMB Desk Officer, room 3208, New Executive Office Building, Washington, DC 20503.

Dated: April 22, 1992.

Edward Michals,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 92-9806 Filed 4-27-92; 8:45 am]

BILLING CODE 3510-07-F

International Trade Administration

[A-351-809]

Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination: Circular Welded Non-Alloy Steel Pipe From Brazil

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: April 28, 1992.

FOR FURTHER INFORMATION CONTACT: Judith Wey or David J. Goldberger, Office of Antidumping Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 377-8320, or (202) 377-4136, respectively.

PRELIMINARY DETERMINATION: We preliminarily determine that circular welded non-alloy steel pipe ("standard pipe") from Brazil is being, or is likely to be, sold in the United States at less than fair value, as provided in section 733 of the Tariff Act of 1930, as amended (the Act). The estimated margins are shown in the "Suspension of Liquidation" section of this notice.

Case History

Since the initiation of this investigation on October 15, 1991, (56 FR 52528, October 21, 1991), the following events have occurred.

On November 8, 1991, the U.S. International Trade Commission (ITC) issued an affirmative preliminary injury determination.

On November 27, 1991, the Department presented an antidumping duty questionnaire to Persico Pizzamiglio S.A. (Persico), which accounts for over 60 percent of the exports of standard pipe to the United States.

Persico submitted questionnaire responses in December 1991 and January 1992. We issued a supplemental questionnaire in February 1992 and received Persico's response in March 1992. We received additional submissions from Persico in April 1992.

On February 4, 1992, petitioners requested, in accordance with 19 CFR 353.15(c), that the Department postpone the preliminary determination to April 21, 1992. The Department granted this request on February 10, 1992 (57 FR 5997, February 19, 1992).

On February 24, 1992, petitioners alleged that Persico sold standard pipe in the home market at prices below the cost of production. On March 17, 1992, the Department determined that it had reasonable grounds to believe or suspect that Persico sold standard pipe below cost in the home market, in accordance with section 733(b) of the Act. The Department issued the Cost of Production and Constructed Value Questionnaire (Section D) to Persico on March 19, 1992. Persico's response to Section D was originally due on April 16, 1992. On March 24, 1992, Persico presented several proposals for limiting the reporting of cost data and stated that full reporting was unnecessary and unduly onerous. On March 26, 1992, we informed Persico that it need only report full cost data for all home market products sold in the months in which there were U.S. sales. On April 6, 1992, we informed Persico that it had the option to limit reporting of cost data to products in its model match concordance. At Persico's request, the Department has granted an extension of time until May 1, 1992, to report cost data. We will consider whether Persico made sales below cost in the home market in the final determination.

On April 16, 1992, Persico requested that, in the event of an affirmative preliminary determination in this investigation, the Department postpone the final determination to no later than 135 days after the date of the publication of the affirmative preliminary determination. (See, the Postponement of Final Determination section of this notice.)

Scope of Investigation

The merchandise subject to this investigation is circular welded non-alloy steel pipes and tubes, of circular cross-section, not more than 406.4mm (16 inches) in outside diameter, regardless of wall thickness, surface finish (black, galvanized, or painted), or end finish (plain end, bevelled end, threaded, or threaded and coupled). These pipes and tubes are generally known as standard pipe, though they may also be called structural or mechanical tubing in certain applications. Standard pipes and tubes are intended for the low pressure conveyance of water, steam, natural gas, air, and other liquids and gases in plumbing and heating systems, air conditioning units, automatic sprinkler systems, and other related uses. Standard pipe may also be used for light load—bearing and mechanical applications, such as for fence tubing, and for protection of electrical wiring, such as conduit shells.

The scope is not limited to standard pipe and fence tubing, or those types of mechanical and structural pipe that are used in standard pipe applications. All carbon steel pipes and tubes within the physical description outlined above are included within the scope of this investigation, except line pipe, oil country tubular goods, boiler tubing, cold-drawn or cold-rolled mechanical tubing, pipe and tube hollows for redraws, finished scaffolding, and finished rigid conduit. Standard pipe that is dual or triple certified/stenciled that enters the U.S. as line pipe of a kind used for oil or gas pipelines is also not included in this investigation.

Imports of these products are currently classifiable under the following Harmonized Tariff Schedule (HTS) subheadings: 7306.30.10.00, 7306.30.50.25, 7306.30.50.32, 7306.30.50.40, 7306.30.50.55, 7306.30.50.85, and 7306.30.50.90. Although the HTS subheadings are provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

Period of Investigation

The period of investigation (POI) is April 1, 1991, through September 30, 1991.

Such or Similar Comparisons

We have determined that all the products covered by this investigation constitute a single category of such or similar merchandise. Where there were no sales of identical merchandise in the home market to compare to U.S. sales, we made similar comparisons on the basis of: (1) Commercial or industry grade/classification; (2) nominal pipe size; (3) wall thickness; (4) surface finish or coating; and (5) end finish. We made adjustments for differences in the physical characteristics of the

merchandise in accordance with section 773(a)(4)(C) of the Act.

Fair Value Comparisons

To determine whether sales of standard pipe from Brazil to the United States were made at less than fair value, we compared the United States price (USP) to the foreign market value (FMV), as specified in the "United States Price" and "Foreign Market Value" sections of this notice.

Persico has reported that it sells standard pipe on an actual weight basis in the home market and on a theoretical weight basis in the United States. Persico has not provided sufficient information to enable the Department to make fair value comparisons on the same weight basis. Therefore, for purposes of the preliminary determination, we have denied Persico's request that we convert U.S. prices from a theoretical to a standard actual weight basis (based on Persico's historical production data), since this conversion still will not allow us to make an "apples to apples" comparison. If Persico provides timely information to permit the conversion of actual home market prices to a theoretical weight basis, we will make price comparisons on such a basis for purposes of the final determination.

United States Price

We based USP on purchase price, in accordance with section 772(b) of the Act, because the subject merchandise was sold to unrelated purchasers in the United States prior to importation and because exporter's sale price (ESP) methodology was not indicated by other circumstances.

We calculated purchase price based on packed, CIF prices to unrelated customers in the United States. We made deductions for foreign inland freight (including foreign inland insurance), foreign brokerage, and ocean freight expenses incurred by Persico. In accordance with section 772(d)(1)(C) of the Act, we added to USP the amount of the Brazilian Social Investment Fund (FINSOCIAL), Industrialized Products (IPI), and Program of Social Integration (PIS) taxes that would have been collected had the Brazilian government taxed the exported merchandise.

Foreign Market Value

In order to determine whether there were sufficient sales of standard pipe in the home market to serve as a viable basis for calculating FMV, we compared the volume of home market sales of standard pipe to the volume of third country sales in accordance with section 773(a)(1)(B) of the Act. We found that the home market was viable for sales of Standard pipe.

We determined Brazil's economy to be hyperinflationary. In order to eliminate the distorative effects of inflation, consistent with past practice, we calculated separate weighted-average FMV's for each month for which home market sales were reported.

We calculated FMV based on packed, CIF prices to unrelated customers in the home market. We made deductions for foreign inland freight expenses (including foreign inland insurance) incurred by Persico. Persico's home market foreign inland freight expenses were significantly higher in certain months in which Persico incurred service and repair expenses. Because we did not have sufficient information to allocate there service and repair expenses over the POI, we calculated an average of Persico's reported monthly foreign inland freight expenses. We deducted home market packing costs and added U.S. packing costs, in accordance with section 773(a)(1)(B) of the Act.

Pursuant to 19 CFR 353.56(a)(2), we made circumstances of sale adjustments, where appropriate, for differences in credit expenses and commissions. Given that the Tax on Circulation of Merchandise (ICMS) rate varies with the destination of the merchandise in the home market, we simply deducted the ICMs tax from foreign market value and made no addition to USP.

Persico claimed a credit benefit on certain U.S. sales. We have determined, however, that Persico's methodology used to calculate credit benefits and expenses appears to grossly overstate the actual benefits received and expenses incurred. Persico's methodology took advantage of interest rates associated with hyperinflationary economies, but failed to use exchange rates that accurately reflected the values of rapidly depreciating currency. For those sales for which Persico claimed a credit benefit, we have made no adjustment for credit benefits and expenses for purposes of the preliminary determination. We will reexamine this issue at the final determination. Persico also failed to report home market indirect selling expenses. Therefore, no offset was made in those cases where commissions were paid on U.S. sales but no commission was paid on the home market sale. We deducted the taxes included in the home market price and added the indirect taxes computed for USP.

In accordance with 19 CFR 353.58, we compared U.S. sales to home market sales made at the same level of trade, when possible. Persico reported that it sold to distributors in the United States and to distributors and end-users in the home market. Thus, when possible, we compared distributor sales to distributor sales. Where there were no sales of such or smaller merchandise at the same commercial level of trade in Brazil, we used sales made at the other level as the most comparable level of trade.

Currency Conversion

No certified rates of exchange, as furnished by the Federal Reserve Bank of New York, were available for the POI. In place of the official certified rates, we used the daily official exchange rates for Brazil published by the Central Bank of Brazil.

In hyperinflationary economies, ordinarily the Department converts movement charges on U.S. sales on the date these charges become payable. In this case, we converted charges on U.S. sales on the date of the shipment, the closest approximation to the date the charges become payable.

Verification

As provided in section 776(b) of the Act, we will verify the information used in making our final determination.

Suspension of Liquidation

In accordance with section 733(d)(1) of the Act, we are directing the Customs Service to suspend liquidation of all entries of standard pipe from Brazil that are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. The Customs Service shall require a cash deposit or posting of a bond equal to the estimated preliminary dumping margins, as shown below. This suspension of liquidation will remain in effect until further notice.

Producer/manufacturer/exporter	Weighted/average margin percentage
Persico Pizzamiglio S.A.	2.66
All others	2.66

ITC Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our determination. If our final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after our final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Postponement of Final Determination

As stated above, in accordance with 19 CFR 353.20(b), Persico has requested that in the event of an affirmative preliminary determination, the Department postpone the final determination. Accordingly, we are postponing the final determination until not later than 135 days after the date of the publication of this notice.

Public Comment

In accordance with 19 CFR 353.38, case briefs or other written comments in at least ten copies must be submitted to the Assistant Secretary for Import Administration no later than July 13, 1992, and for rebuttal briefs no later than July 20, 1992. In accordance with 19 CFR 353.38(b), we will hold a public hearing, if requested, to afford interested parties an opportunity to comment on arguments raised in case or rebuttal briefs. Tentatively, the hearing will be held on July 22, 1992, at 9:30 a.m. at the U.S. Department of Commerce, room 3708, 14th Street and Constitution Avenue NW., Washington, DC 20230. Parties should confirm by telephone the time, date, and place of the hearing 48 hours before the scheduled time.

Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce, room B-099, within ten days of the publication of this notice. requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. In accordance with 19 CFR 353.38(b), oral presentations will be limited to issues raised in the briefs.

This determination is published pursuant to section 733(f) of the Act and 19 CFR 353.15(a)(4).

Dated: April 21, 1992.

Alan M. Dunn,

Assistant Secretary for Import Administration.

[FR Doc. 92-9880 Filed 4-27-92; 8:45 am]

BILLING CODE 3510-DS-M

[A-580-809]

Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination: Circular Welded Non-Alloy Steel Pipe From the Republic of Korea

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: April 28, 1992.

FOR FURTHER INFORMATION CONTACT: Mark Wells or Andrew McGilvray, Office of Antidumping Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 377-3003 or (202) 377-0108, respectively.

PRELIMINARY DETERMINATION: We preliminarily determine that circular welded non-alloy steel pipe ("standard pipe") from the Republic of Korea (Korea) is being, or is likely to be, sold in the United States at less than fair value, as provided in section 733 of the Tariff Act of 1930, as amended (the Act). The estimated margins are shown in the "Suspension of Liquidation" section of this notice.

Case History

Since the initiation of this investigation on October 15, 1991, (56 FR 53528, October 21, 1991), the following events have occurred.

On November 8, 1991, the U.S. International Trade Commission (ITC) issued an affirmative preliminary injury determination.

On November 27, 1991, the Department presented antidumping duty questionnaire to Hyundai Steel Pipe Co., Ltd., Korea Steel Pipe Co., Ltd. (KSP), Mason Steel Tube Works Co., Ltd., and Pusan Steel Pipe Co., Ltd. (PSP). These four respondents accounted for at least 60 percent of the exports of standard pipe to the United States.

Early in the investigation, Masan indicated an intention to file a voluntary questionnaire response. When we issued the questionnaire we advised Masan that as a questionnaire recipient, it would be treated as a mandatory respondent in the same manner as other mandatory respondents in the investigation, and that the standard for application of best information available (BIA), if necessary, would be in accordance with the standard applied to all other respondents.

The respondents submitted sales questionnaire responses in December 1991 and January 1992. We issued supplemental sales questionnaires in February 1992 and received the responses in March 1992.

On February 4, 1992, petitioners requested that the Department postpone the preliminary determination until April 21, 1992, pursuant to 19 CFR 353.15(c). The Department granted this request on February 10, 1992. (57 FR 5997, February 19, 1992.)

In submissions dated February 13 and 18, 1992, petitioners alleged that Hyundai, KSP, and PSP sold standard pipe in the home market at prices below the cost of production. On February 27, 1992, the Department determined that it had reasonable grounds to believe or suspect that Hyundai, KSP, and PSP had sold standard pipe below cost in the home market, and therefore initiated a cost investigation, in accordance with section 773(b) of the Act. The Department issued a Cost of Production and Constructed Value Questionnaire to Hyundai, KSP, and PSP on March 5, 1992. Responses to the questionnaire were originally due on April 6, 1992. However, in submissions on March 17 and March 19, 1992, respondents presented several proposals for limiting reporting of cost data and stated that full reporting was unnecessary and unduly burdensome. On April 6, 1992, the Department accepted respondents' proposal to limit reporting of cost data to products in the respondents' model match concordances. At respondents' request, the Department has also granted an extension of time until April 22, 1992, to report cost data. We will consider whether respondents made sales below cost in the home market in the final determination.

On March 31, 1992, respondents Hyundai, KSP, and PSP requested that, in the event of an affirmative preliminary determination in this investigation, the Department postpone the final determination to 135 days after the date of the publication of the affirmative preliminary determination. See Postponement of Final Determination section of this notice.

Scope of Investigation

The merchandise subject to this investigation is circular welded non-alloy steel pipes and tubes, of circular cross-section, not more than 406.4mm (16 inches) in outside diameter, regardless of wall thickness, surface finish (black, galvanized, or painted), or end finish (plain end, bevelled end, threaded, or threaded and coupled). These pipes and tubes are generally known as standard pipe, though they may also be called structural or mechanical tubing in certain applications. Standard pipes and tubes are intended for the low pressure conveyance of water, steam, natural gas, air, and other liquids and gases in plumbing and heating systems, air conditioning units, automatic sprinkler systems, and other related uses. Standard pipe may also be used for light load-bearing and mechanical applications, such as for fence tubing, and for protection of electrical wiring, such as conduit shells.

The scope is not limited to standard pipe and fence tubing, or those types of

mechanical and structural pipe that are used in standard pipe applications. All carbon steel pipes and tubes within the physical description outlined above are included within the scope of this investigation, except line pipe, oil country tubular goods, boiler tubing, cold-drawn or cold-rolled mechanical tubing, pipe and tube hollows for redraws, finished scaffolding, and finished rigid conduit. Standard pipe that is dual or triple certified/stenciled that enters the U.S. as line pipe of a kind used for oil or gas pipelines is also not included in this investigation.

Imports of these products are currently classifiable under the following Harmonized Tariff Schedule (HTS) subheadings: 7306.30.10.00, 7306.30.50.25, 7306.30.50.32, 7306.30.50.40, 7306.30.50.55, 7306.30.50.85, and 7306.30.50.90. Although the HTS subheadings are provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

Period of Investigation

The period of investigation (POI) is April 1, 1991, through September 30, 1991.

Such or Similar Comparisons

We have determined that all the products covered by this investigation constitute a single category of such or similar merchandise. Where there were no sales of identical merchandise in the home market to compare to U.S. sales, we made comparisons on the basis of: (1) Commercial or industry grade/classification; (2) nominal pipe size; (3) wall thickness; (4) surface finish or coating; and (5) end finish. We made adjustments for differences in the physical characteristics of the merchandise, in accordance with section 773(a)(4)(C) of the Act.

We made sales comparisons on the basis of theoretical weight, the weight basis on which respondents reported that U.S. sales were made.

Fair Value Comparisons

To determine whether sales of standard pipe from Korea to the United States were made at less than fair value, we compared the United States price (USP) to the foreign market value (FMV), as specified in the "United States Price" and "Foreign Market Value" sections of this notice.

United States Price

For Hyundai, KSP, Masan, and PSP, we based USP on purchase price, in accordance with section 772(b) of the Act, when the subject merchandise was sold to unrelated purchasers in the United States prior to importation and because exporter's sale price (ESP) methodology, in those instances, was not otherwise indicated.

In addition, for Hyundai, KSP, and PSP, where certain sales to the first unrelated purchaser took place after importation into the United States, we also based USP on ESP, in accordance with section 772(c) of the Act.

For Hyundai, KSP, and PSP, because a value-added tax (VAT) was paid on home market sales but not on U.S. sales, we added to the U.S. selling price the amount of the VAT that would have been collected if the export sales had been taxed.

A. Hyundai

For Hyundai, we calculated purchase price based on packed, f.o.b., c&f, c.o.d., or ex-dock duty paid prices to unrelated customers in the United States. We made deductions, where appropriate, for foreign brokerage and handling, foreign inland freight, wharfage, ocean freight, marine insurance, U.S. duties, and U.S. brokerage and handling.

We calculated ESP based on packed ex-warehouse prices to unrelated customers in the United States. We made deductions, where appropriate, for foreign brokerage and handling, foreign inland freight, wharfage, ocean freight, marine insurance, U.S. duties, U.S. inland freight, U.S. brokerage and handling, credit expenses, and indirect selling expenses, including inventory carrying costs.

We disallowed Hyundai's claimed duty drawback adjustment because the firm failed to calculate drawback in the manner requested by the Department and because Hyundai failed to provide sufficient documentation linking import duties paid to claimed duty drawback. See Certain Circular Welded Carbon Steel Pipes and Tubes from Thailand: Final Results of Antidumping Duty Administration Review (56 FR 58355, 58358 (1991)) (Thailand Pipes and Tubes). If supplemental information is submitted and verified we will reconsider this adjustment in the final determination.

B. KSP

For KSP, we calculated purchase price based on packed, c & f c.i.f., or ex-dock duty paid prices to unrelated customers in the United States. We made deductions, where appropriate, for foreign brokerage and handling, foreign inland freight, wharfage, security charges, ocean freight, marine insurance, U.S. duties, U.S. inland freight, U.S. brokerage and handling, and discounts.

We made an adjustment for duty drawback pursuant to section 772(d)(1)(B) of the Act. For certain purchase price sales made through KSP's U.S. subsidiary, we recalculated credit expenses because KSP failed to report credit and related expenses incurred on these sales.

We calculated ESP based on packed, ex-dock duty paid prices, to unrelated customers in the United States. We made deductions, where appropriate, for foreign brokerage and handling, foreign inland freight, wharfage, ocean freight, marine insurance, U.S. duties, U.S. inland freight, U.S. warranties, U.S. brokerage and handling, discounts, credit expenses, and indirect selling expenses, including inventory carrying costs. We recalculated credit to reflect the fact that discounts had been incurred on sales to the United States.

We disallowed KSP's claimed duty drawback adjustment for ESP sales because it failed to calculate drawback in the manner requested by the Department and because KSP failed to provide sufficient documentation linking import duties paid to claimed duty drawback. See Thailand Pipes and Tubes, supra. If supplemental information is submitted and verified we will reconsider this adjustment in the final determination.

C. Masan

For Masan, we calculated purchase price based on packed, c & f, c.i.f., or ex-dock duty paid prices to unrelated customers in the United States. We made deductions, where appropriate, for foreign inland freight, ocean freight, marine insurance, U.S. duties, and U.S. brokerage and handling. For Masan's U.S. sales for which it provided no third country model matches, we used BIA to determine a margin for these sales. As BIA, we used the highest margin calculated on any of Masan's individual U.S. sales.

D. PSP

For PSP, we calculated purchase price based on packed, f.o.b., c & f, or c.i.f., prices to unrelated customers in the United States. We made deductions, where appropriate, for foreign brokerage and handling, foreign inland freight, wharfage, ocean freight, marine insurance, U.S. duties, U.S. inland freight, U.S. brokerage and handling, and discounts. In addition we recalculated credit to reflect the fact that discounts had been incurred on certain sales to the United States.

We calculated ESP based on packed c.i.f., or ex-dock duty paid prices, to unrelated customers in the United

States. We made deductions, where appropriate, for foreign brokerage and handling, foreign inland freight, wharfage, ocean freight, marine insurance, U.S. duties, U.S. inland freight, U.S. brokerage and handling, discounts, credit expenses, and indirect selling expenses, including inventory carrying costs. We recalculated credit to reflect the fact that discounts had been incurred on sales to the United States.

PSP has requested that the Department exclude from its analysis U.S. sales of returned goods because these were not in the ordinary course of trade. We denied PSP's request because the ordinary course of trade exclusion is for foreign market value only (see section 773(a)(1)(A) of the Act). Although, in an investigation, the Department may exclude aberrational sales from its analysis, PSP has not provided any information to demonstrate that such an exclusion is warranted. In addition, because PSP did not provide charges and adjustments for these sales, we used BIA to determine a margin for these sales. As BIA, we used the highest margin calculated on any of PSP's individual U.S. sales.

We disallowed PSP's claimed duty drawback adjustment because it failed to calculate drawback in the manner requested by the Department. PSP failed to provide sufficient support documentation linking import duties paid to claimed duty drawback for purchase price sales. See Thailand Pipes and Tubes, *supra*. If supplemental information is submitted and verified we will reconsider this adjustment in the final determination.

Foreign Market Value

In order to determine whether there were sufficient sales of standard pipe in the home market to serve as a viable basis for calculating FMV, we compared the volume of home market sales of standard pipe to the volume of third country sales of the same product in accordance with section 773(a)(1)(B) of the Act. We found that the home market was viable for sales of standard pipe by Hyundai, KSP, and PSP. For Masan, the home market was not viable and we based FMV on sales to Japan, because Japan was Masan's only third country market and the volume of Masan's Japanese sales was at least five percent of its U.S. sales.

In accordance with 19 CFR 353.58, we compared U.S. sales to home market sales made at the same level of trade, where possible. For comparison to purchase prices sales, pursuant to section 773(a)(4)(B) and 19 CFR 353.56(a)(2), we made circumstance of sale adjustments, where appropriate, for differences in credit expenses. For comparison to ESP sales, we made deductions for credit expenses. For all respondents, we deducted home market packing costs and added U.S. packing costs. For Hyundai, KSP, and PSP, we also made a circumstance of sale adjustment for the difference between VAT on home market sales and that which would have been collected on U.S. sales if the export sales had been taxed.

For comparisons to ESP sales, we deducted from FMV the weighted-average home market indirect selling expenses, including inventory carrying costs, up to the amount of indirect selling expenses incurred on U.S. sales, in accordance with 19 CFR 353.56(b)(2).

A. Hyundai

For Hyundai, we calculated FMV based on ex-factory, delivered, or freight-equalized prices to unrelated customers in the home market. We denied Hyundai's claim that the Department should use its sales to related parties because Hyundai examined only 0.03 percent of home market sales, thus failing to establish that sales to related parties were made at arm's length. We made deductions for inland freight.

For purchase price sales, we recalculated credit expense using the date of shipment from Korea.

B. KSP

For KSP, we calculated FMV based on ex-factory, delivered or freight-equalized prices to unrelated customers in the home market. We made deductions for inland freight.

For certain purchase price sales made through KSP's U.S. subsidiary, we recalculated credit expenses because KSP failed to report all credit and related expenses incurred on these sales.

C. Masan

We calculated FMV based on c & f Japan port, ex-dock, or delivered prices to unrelated customers in the third country. We made deductions, where appropriate, for Korean inland freight, ocean freight, marine insurance, brokerage and handling, and Japanese inland freight.

D. PSP

For PSP, we calculated FMV based on free on truck, delivered, delivered and unloaded, or freight-equalized prices to both unrelated and related customers in the home market. We used PSP's sales to related customers in the home market. We used PSP's sales to related customers because PSP, through an examination of its entire home market database, established that related party sales were at arm's length. We made deductions for inland freight.

For certain purchase price sales, we recalculated credit expense using the date of shipment from Korea.

Currency Conversion

We made currency conversions based on the official exchange rates in effect on the dates of the U.S. sales as certified by the Federal Reserve Bank.

Verification

As provided in section 776(b) of the Act, we will verify the information used in making our final determination.

Suspension of Liquidation

In accordance with section 733(d)(1) of the Act, we are directing the Customs Service to suspend liquidation of all entries of standard pipe from Korea that are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. The Customs Service shall require a cash deposit or posting of a bond equal to the estimated preliminary dumping margins, as shown below. This suspension of liquidation will remain in effect until further notice.

Producer/manufacturer/exporter	Weighted-average margin percentage
Hyundai Steel Pipe Co., Ltd	2.09
Korea Steel Pipe Co., Ltd	2.71
Masan Steel Tube Co	22.68
Pusan Steel Pipe Co., Ltd	17.11
All others	6.27

ITC Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our determination. If our final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after our final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Postponement of Final Determination

As stated above, in accordance with 19 CFR 353.20(b), respondents who account for a significant portion of the merchandise covered by this proceeding have requested that in the event of an affirmative determination the Department postpone the final determination. Accordingly, we are postponing the date of the final determination until not later than 135

days after the date of publication of this notice.

Public Comment

In accordance with 19 CFR 353.38, case briefs or other written comments in at least ten copies must be submitted to the Assistant Secretary for Import Administration no later than July 16, 1992, and for rebuttal briefs no later than July 23, 1992. In accordance with 19 CFR 353.38(b), we will hold a public hearing, if requested, to afford interested parties an opportunity to comment on arguments raised in case or rebuttal briefs. Tentatively, the hearing will be held on July 27, 1992, at 10 a.m. at the U.S. Department of Commerce, room 3708, 14th Street and Constitution Avenue NW., Washington, DC 20230. Parties should confirm by telephone the time, date, and place of the hearing 48 hours before the scheduled time.

Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce, Room B-099, within ten days of the publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. In accordance with 19 CFR 353.38(b), oral presentations will be limited to issues raised in the briefs.

This determination is published pursuant to section 733(f) of the Act and 19 CFR 353.15(a)(4).

Dated: April 21, 1992.

Alan M. Dunn,

Assistant Secretary for Import Administration.

[FR Doc. 92-9881 Filed 4-27-92; 8:45 am]

BILLING CODE 3510-DS-M

[A-201-805]

Preliminary Determination of Sales at Less Than Fair Value: Circular Welded Non-Alloy Steel Pipe From Mexico

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: April 28, 1992.

FOR FURTHER INFORMATION CONTACT: David J. Goldberger or Judith Wey, Office of Antidumping Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 377-4136, or (202) 377-8320, respectively.

PRELIMINARY DETERMINATION: We preliminarily determine that circular welded non-alloy steel pipe ("standard pipe") from Mexico is being, or is likely to be, sold in the United States at less than fair value, as provided in section 733 of the Tariff Act of 1930, as amended (the Act). The estimated margins are shown in the "Suspension of Liquidation" section of this notice.

Case History

Since the initiation of this investigation on October 15, 1991, (56 FR 52528, October 21, 1991), the following events have occurred.

On November 8, 1991, the U.S. International Trade Commission (ITC) issued an affirmative preliminary injury determination.

On November 27, 1991, the Department presented an antidumping duty questionnaire to HYLSA, S.A. de C.V. (HYLSA), which accounts for over 60 percent of the exports of the standard pipe to the United States, and to Industrias Monterrey, S.A. (IMSA), an exporter of the subject merchandise which has indicated an intention to file a voluntary questionnaire response.

HYLSA submitted questionnaire responses in December 1991 and January 1992. In January 1992, IMSA stated that it would not respond to the Department's questionnaire. We issued a supplemental questionnaire to HYLSA on January 30, 1992 and received this response in February 1992. HYLSA submitted additional information in March and April, 1992.

On February 4, 1992, petitioners requested, in accordance with 19 CFR 353.15(c), that the Department postpone the preliminary determination to April 21, 1992. The Department granted this request on February 10, 1992. (57 FR 5997, February 19, 1992.)

Scope of Investigation

The merchandise subject to this investigation is circular welded non-alloy steel pipes and tubes, of circular cross-section, not more than 406.4mm (16 inches) in outside diameter, regardless of wall thickness, surface finish (black, galvanized, or painted), or end finish (plain end, bevelled end, threaded, or threaded and coupled). These pipes and tubes are generally known as standard pipe, though they may also be called structural or mechanical tubing in certain applications. Standard pipes and tubes are intended for the low pressure conveyance of water, steam, natural gas, air, and other liquids and gases in plumbing and heating systems, air conditioning units, automatic sprinkler systems, and other related uses. Standard pipe may also be used for light load-bearing and mechanical applications, such as for fence tubing, and for protection of electrical wiring, such as conduit shells.

The scope is not limited to standard pipe and fence tubing, or those types of mechanical and structural pipe that are used in standard pipe applications. All carbon steel pipes and tubes within the physical description outlined above are included within the scope of this investigation, except line pipe, oil country tubular goods, boiler tubing, cold-drawn or cold-rolled mechanical tubing, pipe and tube hollows for redraws, finished scaffolding, and finished rigid conduit. Standard pipe that is dual or triple certified/stenciled that enters the U.S. as line pipe of a kind used for oil or gas pipelines is also not included in this investigation.

Imports of these products are currently classifiable under the following Harmonized Tariff Schedule (HTS) subheadings: 7306.30.10.00, 7306.30.50.25, 7306.30.50.32, 7306.30.50.40, 7306.30.50.55, 7306.30.50.85, and 7306.30.50.90.

Although the HTS subheadings are provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

Period of Investigation

The period of investigation (POI) is April 1, 1991, through September 30, 1991.

Such or Similar Comparisons

We have determined that all the products covered by this investigation constitute a single category of such or similar merchandise. Where there were no sales of identical merchandise in the home market to compare to U.S. sales, we made similar comparisons on the basis of: (1) Commercial or industry grade/classification; (2) nominal pipe size; (3) wall thickness; (4) surface finish or coating; and (5) end finish. We made adjustments for differences in the physical characteristics of the merchandise in accordance with section 773(a)(4)(C) of the Act.

Fair Value Comparisons

To determine whether sales of standard pipe from Mexico to the United States were made at less than fair value, we compared the United States price (USP) to the foreign market value (FMV), as specified in the "United States Price" and "Foreign Market Value" sections of this notice.

Use of Best Information Available

For IMSA, we used best information available (BIA) as required by section 776(c) of the Act because IMSA did not

respond to the antidumping duty questionnaire. As stated above under Case History, we issued a questionnaire to IMSA on November 27, 1991. On that same day, we advised counsel for IMSA that IMSA was being considered a mandatory respondent in the investigation. Counsel for IMSA was told that, as a mandatory respondent, IMSA would be accorded the same treatment as all other mandatory respondents. For example, we fully intended that deficiency letters would be issued to enable IMSA to correct shortcomings in its response. We also informed counsel for IMSA that the application of BIA, if necessary, would be accordance with that applied to all other respondents. Counsel for IMSA indicated that IMSA understood the Department's clarifications and that IMSA desired to be a full participant in the investigation. (see Memorandum to the File dated December 6, 1991).

On December 19, 1991, IMSA notified the Department that it would not respond to the questionnaire. In response, the Department informed IMSA that its failure to respond to the questionnaire required the Department to consider IMSA an uncooperative respondent. Further, the Department stated that since it considered IMSA a mandatory respondent, the Department would assign IMSA a margin based on BIA. IMSA stated that it was aware of the consequences of not responding (see Memorandum to the File dated December 19, 1991). IMSA submitted a letter on January 21, 1992, objecting to its classification as a mandatory respondent and arguing that it should be subject to the "all others" rate, rather than a rate based on BIA.

For purposes of this preliminary determination, the Department continues to regard IMSA as a mandatory respondent in this investigation. Since IMSA did not respond to our antidumping duty questionnaire, we have assigned it a margin based on BIA. As BIA, we used the higher of a) the highest margin calculated from the petition for IMSA, or b) the calculated margin for HYLSA. In this instance, we used the highest margin calculated from the petition.

United States Price

We based USP on purchase price, in accordance with section 772(b) of the Act, because the subject merchandise was sold to unrelated purchasers in the United States prior to importation and because exporter's sale price (ESP) methodology was not indicated by other circumstances.

A. HYLSA

For HYLSA, we calculated purchase price based on delivered at border or delivered at border, duty paid prices. We made deductions for foreign inland freight expenses incurred by HYLSA. No further deductions for movement expenses were made since these expenses were not included in the gross price. In accordance with section 772(d)(1)(C) of the Act, we also added to USP the amount of the Mexican value added tax (VAT) that would have been collected had the Mexican government taxes the exported merchandise. We added duty drawback pursuant to section 772(d)(1)(B) of the Act.

B. IMSA

As BIA, we based U.S. price on the average customs value of standard pipe imported from Mexico during the second quarter of 1991, as provided in the petition.

Foreign Market Value

In order to determine whether there were sufficient sales of standard pipe in the home market to serve as a viable basis for calculating FMV, we compared the volume of home market sales of standard pipe to the volume of third country sales, in accordance with section 773(a)(1)(B) of the Act. We found that the home market was viable for sales of standard pipe.

A. HYLSA

We calculated FMV based on ex-works prices to unrelated customers in the home market. We made deductions, where appropriate, for discounts, rebates, and inland freight expenses incurred by HYLSA. No further deductions for movement expenses were made since these expenses were not included in the gross price. We deducted home market packing costs and added U.S. packing costs, in accordance with section 773(a)(1)(B) of the Act.

Pursuant to 19 CFR 353.56(a)(2), we made circumstance of sale adjustments, where appropriate, for differences in credit expenses and late payment fees. Finally, we made a circumstance of sale adjustment for differences in the amount of VAT. We did not make a claimed adjustment for steel supplier rebates on materials as these rebates are not considered a circumstance of sale.

HYLSA did not include packing expenses in its sales listings. We calculated packing expenses in both markets using information in the questionnaire response as BIA.

We recalculated credit expenses in both markets to adjust the credit base to fully account for all expenses borne by HYLSA prior to customer payment.

In accordance with 19 CFR 353.58, we compared U.S. sales to home market sales made at the same or most comparable commercial level of trade. HYLSA reported that it sold to industrial end-users and distributors in the United States, and industrial end-users, distributors, and retailers in the home market. Thus, when possible, we compared end-user sales to end-user sales, and distributor sales to distributor sales. However, we noted an inconsistency in HYLSA's classification of a particular home market customer. We will examine carefully the level of trade classifications at verification.

B. IMSA

As BIA, we based FMV on IMSA's home market price lists, as included in the petition.

Currency Conversion

No certified rates of exchange, as furnished by the Federal Reserve Bank of New York, were available for the POI. In place of the official certified rates, we used the average monthly or quarterly exchange rates published by the International Monetary Fund.

Verification

As provided in section 776(b) of the Act, we will verify the information used in making our final determination.

Suspension of Liquidation

In accordance with section 733(d)(1) of the Act, we are directing the Customs Service to suspend liquidation of all entries of standard pipe from Mexico that are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. The Customs Service shall require a cash deposit or posting of a bond equal to the estimated preliminary dumping margins, as shown below. This suspension of liquidation will remain in effect until further notice.

Producer/manufacturer/exporter	Weighted-average margin percentage
HYLSA, S.A. de C.V	27.54
Industrias Monterrey, S.A	96.29
All others	28.03

ITC Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our determination. If our final determination is affirmative, the ITC will determine

before the later of 120 days after the date of this preliminary determination or 45 days after our final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Public Comment

In accordance with 19 CFR 353.38, case briefs or other written comments in at least ten copies must be submitted to the Assistant Secretary for Import Administration no later than June 4, 1992, and for rebuttal briefs no later than June 11, 1992. In accordance with 19 CFR 353.38(b), we will hold a public hearing, if requested, to afford interested parties an opportunity to comment on arguments raised in case or rebuttal briefs. Tentatively, the hearing will be held on June 15, 1992, at 2 p.m. at the U.S. Department of Commerce, room 3708, 14th Street and Constitution Avenue NW., Washington, DC 20230. Parties should confirm by telephone the time, date, and place of the hearing 48 hours before the scheduled time.

Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce, Room B-099, within ten days of the publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. In accordance with 19 CFR 353.38(b), oral presentations will be limited to issues raised in the briefs.

This determination is published pursuant to section 733(f) of the Act and 19 CFR 353.15(a)(4).

Dated: April 21, 1992.

Alan M. Dunn,

Assistant Secretary for Import Administration.

[FR Doc. 92-9882 Filed 4-27-92; 8:45 am]

BILLING CODE 3510-DS-M

[A-485-802]

Preliminary Determination of Sales at Less Than Fair Value: Circular Welded Non-Alloy Steel Pipe From Romania

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: April 28, 1992.

FOR FURTHER INFORMATION CONTACT: David J. Goldberger or Judith Wey, Office of Antidumping Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 377-4136, or (202) 377-8320, respectively.

PRELIMINARY DETERMINATION: We preliminarily determine that circular welded non-alloy steel pipe ("standard pipe") from Romania is being, or is likely to be, sold in the United States at less than fair value, as provided in section 733 of the Tariff Act of 1930, as amended (the Act). The estimated margins are shown in the "Suspension of Liquidation" section of this notice.

Case History

Since the initiation of the investigation on October 15, 1991, (56 FR 52528, October 21, 1991), the following events have occurred.

On November 8, 1991, the U.S. International Trade Commission (ITC) issued an affirmative preliminary injury determination. On that day, the Department sent letters to interested parties requesting comments as to whether Romania should continue to be treated as a nonmarket economy country (NME), as provided for under section 773(c) of the Act. To date, no party has contested Romania's continued treatment as an NME.

On November 27, 1991, the Department presented an antidumping duty questionnaire to Metalexportimport, S.A. (MEI), a trading company which accounts for all exports of standard pipe to the United States.

MEI submitted questionnaire responses in December 1991 and January 1992. We issued a supplemental questionnaire in January 1992 and received a response during February 1992.

On February 4, 1992, petitioners requested that the Department postpone the preliminary determination to April 21, 1992, pursuant to 19 CFR 353.15(c). The Department granted this request on February 10, 1992 (57 FR 5997, February 19, 1992).

The Department conducted verification of MEI's response at MEI headquarters in Bucharest, Romania, and at the facilities of the standard pipe manufacturer, Tepro, S.A. (Tepro), in Iasi, Romania, from March 16 through 19, 1992. Subsequently, in March 1991, MEI submitted revisions to its response based on the verification results.

Scope of Investigation

The merchandise subject to this investigation is circular welded non-alloy steel pipes and tubes, of circular cross-section, not more than 406.4mm (16 inches) in outside diameter, regardless of wall thickness, surface finish (black, galvanized, or painted), or end finish (plain end, bevelled end, threaded, or threaded and coupled). These pipes and tubes are generally known as standard pipe, though they may also be called structural or mechanical tubing in certain applications. Standard pipes and tubes are intended for the low pressure conveyance of water, steam, natural gas, air, and other liquids and gases in plumbing and heating systems, air conditioning units, automatic sprinkler systems, and other related uses. Standard pipe may also be used for light load-bearing and mechanical applications, such as for fence tubing, and for protection of electrical wiring, such as conduit shells.

The scope is not limited to standard pipe and fence tubing, or those types of mechanical and structural pipe that are used in standard pipe applications. *All* carbon steel pipes and tubes within the physical description outlined above are inclined within the scope of this investigation, except line pipe, oil country tubular goods, boiler tubing, cold-drawn or cold-rolled mechanical tubing, pipe and tube hollows for redraws, finished scaffolding, and finished rigid conduit. Standard pipe that is dual or triple certified/stenciled that enters the U.S. as line pipe of a kind used for oil or gas pipelines is also not included in this investigation.

Imports of these products are currently classifiable under the following Harmonized Tariff Schedule (HTS) subheadings: 7306.30.10.00, 7306.30.50.25, 7306.30.50.32, 7306.30.50.40, 7306.30.50.55, 7306.30.50.85, and 7306.30.50.90.

Although the HTS subheadings are provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

Period of Investigation

The period of investigation (POI) is April 1, 1991, through September 30, 1991.

Fair Value Comparisons

To determine whether sales of standard pipe from Romania to the United States were made at less than fair value, we compared the United States price (USP) to the foreign market value (FMV), as specified in the "United States Price" and "Foreign Market Value" sections of this notice.

United States Price

We based USP on purchase price, in accordance with section 772(b) of the Act, because the subject merchandise was sold to unrelated purchasers in the United States prior to importation and because exporter's sale price (ESP)

methodology was not indicated by other circumstances.

We calculated purchase price based on packed, FOB Romanian port prices to unrelated customers in the United States. We made deductions for foreign inland freight and foreign brokerage and handling. Since MEI reported the use of Romanian-sourced providers for these services, we based the deduction for freight on published freight rates in Thailand, the preferred surrogate country in this case (see **Surrogate Country** section of this notice). For brokerage and handling, we used an amount based on the verified experience of a Thai producer of steel products, as contained in the public file of a contemporaneous antidumping investigation, Certain Carbon Steel Butt-Weld Pipe Fittings from Thailand.

Foreign Market Value

Section 773(c)(1) of the Act provides that the Department shall determine FMV using a factors of production methodology if (1) the merchandise is exported from an NME, and (2) the information does not permit the calculation of FMV using home market prices, third country prices, or constructed value under section 773(a) of the Act.

In all past cases (e.g., Final Determination of Sales at Less than Fair Value: Antifriction Bearings (Other than Tapered Roller Bearings) and Parts Thereof From Romania, 54 FR 19109 (May 3, 1989)), the Department has treated Romania as an NME. We requested comments on continuing this treatment, as noted above. To this date, no party has suggested that Romania is no longer an NME, nor has any party claimed that a market-oriented industry exists for the standard pipe industry or any of its inputs, based on the criteria set forth in Preliminary Determination of Sales at Less than Fair Value: Sulfanilic Acid from the People's Republic of China, 57 FR 9409, (March 18, 1992). Therefore, in accordance with section 773(c) of the Act, the Department is required to determine FMV on the basis of the factors of production utilized in producing the subject merchandise, as valued in a surrogate country.

Surrogate Country

Section 773(c) of the Act requires the Department to value the factors of production, to the extent possible, in one or more market economy countries that are at a level of economic development comparable to that of the NME and that are significant producers of comparable merchandise. The Department has determined that Thailand, Turkey, Argentina, Malaysia, and Chile are the most comparable to Romania in terms of overall economic development, based on per capita gross national product (GNP), the national distribution of labor, and growth rate in per capita GNP. Of the countries that are comparable to Romania and produce comparable merchandise, Thailand is the most comparable and therefore is the preferred surrogate country for purposes of valuing the factors of production used in producing the subject merchandise. We used Turkish factor values where Thai factor values were not obtainable, since Turkey is the next most comparable surrogate country to Romania. Data for valuing the factors of production were obtained from publicly available sources, including data submitted by the petitioners and MEI, and from the U.S. embassy in Turkey. MEI also submitted Thai values for certain materials based on its research. Although requested, no information for valuing the factors was received from the U.S. embassy in Thailand.

We calculated FMV based on factors of production reported by the exporter, MEI. The factors used to produce standard pipe include materials, energy, water, and labor. To value all factors except methane, we relied on publicly available Thai data. As we were unable to obtain a Thai value for methane, we relied on data from the U.S. embassy in Turkey. Where appropriate, the factor values were inflated to POI levels using wholesale price indices published by the International Monetary Fund.

Based on findings at verification, we made the following revisions to MEI's reported factors of production:

(a) We corrected minor errors in the reported steel consumption and recoverable steel scrap figures for certain pipes, using information from the verification and the questionnaire response;

(b) MEI did not report factor inputs for plastic thread protectors included with threaded and coupled pipe. We calculated the consumption factor using weight and quantity data gathered at verification, and valued this factor with a Thai value for plastic obtained from a published, publicly available source.

To calculate FMV, the reported factors of production were multiplied by the appropriate Thai and Turkish values for the various components. We added an amount for the delivery of steel inputs to the factory to arrive at a delivered cost for steel. To the sum of material and labor values, we added a percentage for factory overhead, based on a Thai producer's verified experience, using information from the public file of the 1987–88 administrative review of Certain Circular Welded Carbon Steel Pipes and Tubes from Thailand, as placed in the record for this investigation by MEI, to the sum of material, labor, energy, and factory overhead values, we added a percentage for selling, general, and administrative expenses, based on a Thai producer's verified experience, as derived from the same source as factory overhead. Since we had no information on profit for Thailand, and the amount reported for a Turkish producer by the U.S. embassy in Turkey was below the statutory minimum of eight percent, we added a percentage for profit based on the statutory minimum of eight percent of general expenses plus cost of materials and fabrication. We also added an amount for packing labor based on Thai wage rates, and an amount for packing materials based on Thai values, to arrive at a constructed FMV for one metric ton of standard pipe.

Currency Conversion

When calculating FMV, we made currency conversions in accordance with 19 CFR 353.60(a). For conversions from Thai currency, we used the official exchange rates as certified by the Federal Reserve Bank. Since no certified rates of exchange were available for Turkish currency, we used the exchange rates published by the International Monetary Fund.

Verfication

We verified the U.S. sales and factors of production information used in making our preliminary determination in this investigation. Standard verification procedures, including examination of relevant sales and production records and original source documents provided by the respondent, were used.

Suspension of Liquidation

In accordance with section 733(d)(1) of the Act, we are directing the Customs Service to suspend liquidation of all entries of standard pipe from Romania that are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. The Customs Service shall require a cash deposit or posting of a bond equal to the estimated preliminary dumping margins, as shown below. This suspension of liquidation will remain in effect until further notice.

Producer/manufacturer/exporter	Weighted-average margin percentage
Metalexportimport, S.A., and all others	37.66

ITC Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our determination. If our final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after our final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Public Comment

In accordance with 19 CFR 353.38, case briefs or other written comments in at least ten copies must be submitted to the Assistant Secretary for Import Administration no later than June 1, 1992, and for rebuttal briefs no later than June 8, 1992. In accordance with 19 CFR 353.38(b), we will hold a public hearing, if requested, to afford interested parties an opportunity to comment on arguments raised in case or rebuttal briefs. Tentatively, the hearing will be held on June 10, 1992, at 10 a.m. at the U.S. Department of Commerce, room 3708, 14th Street and Constitution Avenue, NW., Washington, DC 20230. Parties should confirm by telephone the time, date, and place of the hearing 48 hours before the scheduled time.

Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce, Room B-099, within ten days of the publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. In accordance with 19 CFR 353.38(b), oral presentations will be limited to issues raised in the briefs.

This determination is published pursuant to section 733(f) of the Act and 19 CFR 353.15(a)(4).

Dated: April 21, 1992.

Alan M. Dunn,

Assistant Secretary for Import Administration.

[FR Doc. 92-9883 Filed 4-27-92; 8:45 am]

BILLING CODE 3510-DS-M

[A-583-814]

Preliminary Determination of Sales at Less Than Fair Value: Circular Welded Non-Alloy Steel Pipe From Taiwan

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: April 28, 1992.

FOR FURTHER INFORMATION CONTACT: Erik Warga, Office of Antidumping Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 377-8922.

PRELIMINARY DETERMINATION: We preliminarily determine that imports of circular welded non-alloy steel pipe ("standard pipe") from Taiwan are being, or are likely to be, sold in the United States at less than fair value (LTFV), as provided in section 733 of the Tariff Act of 1930, as amended (the Act). Because respondents failed to provide adequate responses to our requests for information, we have based our preliminary LTFV calculations on the best information otherwise available (BIA). In this instance, we have determined BIA to be information contained in the petition. The estimated margins are shown in the "Suspension of Liquidation" section of this notice.

Case History

Since the initiation of this investigation on October 15, 1991, (56 FR 52528, October 21, 1991), the following events have occurred.

On November 8, 1991, the U.S. International Trade Commission (ITC) issued an affirmative preliminary injury determination in this case.

On November 27, 1991, the Department presented antidumping duty questionnaires to Kao Hsing Chang Iron & Steel Corp. ("KHC") and Yieh Hsing Enterprise Co., Ltd., ("Yieh Hsing"). These two respondents accounted for at least 60 percent of the exports of standard pipe to the United States.

The respondents submitted sales questionnaire responses in December 1991 and January 1992. We issued deficiency letters to both respondents on February 12, 1992, and received responses on February 29, 1991, (for KHC) and on March 9, 1922 (for Yieh Hsing). We issued supplemental deficiency letters on March 31, 1992, and provided KHC and Yieh Hsing copies of a decision memorandum indicating that we would not use their responses for our preliminary determination. On April 14, 1992, KHC filed a response to our supplemental deficiency letter. Yieh Hsing did not respond to our supplemental deficiency letter.

On February 4, 1992, petitioners requested that the Department postpone the preliminary determination to April 21, 1992, pursuant to 19 CFR 353.15(c). The Department granted this request on February 10, 1992. (57 FR 5997, February 19, 1992.)

Scope of Investigation

The merchandise subject to this investigation is (1) circular welded non-alloy steel pipes and tubes, of circular cross-section over 114.3 millimeters (4.5 inches), but not over 406.4 millimeters (16 inches), in outside diameter, with a wall thickness of 1.65 millimeters (0.065 inches) or more, regardless of surface finish (black, galvanized, or painted), or end finish (plain end, bevelled end, threaded, or threaded and coupled); and (2) circular welded non-alloy steel pipes and tubes, or circular cross-section less than 406.4 millimeters (16 inches), with a wall thickness of less than 1.65 millimeters (0.065 inches), regardless of surface finish (black, galvanized, or painted) or end finish (plain end, bevelled end, threaded, or threaded and coupled). These pipes and tubes are generally known as standard pipe, though they may also be called structural or mechanical tubing in certain applications. Standard pipes and tubes are intended for the low pressure conveyance of water, steam, natural gas, air, and other liquids and gases in plumbing and heating systems, air conditioning units, automatic sprinkler systems, and other related uses. Standard pipe may also be used for light load-bearing and mechanical applications, such as for fence tubing, and for protection of electrical wiring, such as conduit shells.

The scope is not limited to standard pipe and fence tubing, or those types of mechanical and structural pipe that are used in standard pipe applications. All carbon steel pipes and tubes, within the physical description outlined above, are included within the scope of this investigation, except line pipe, oil country tubular goods, boiler tubing, cold-drawn or cold-rolled mechanical tubing, pipe and tube hollows for redraws, finished scaffolding, and finished rigid conduit. Standard pipe that is dual or triple certified/stenciled that enters the U.S. as line pipe of a kind used for oil or gas pipelines is also not included in this investigation.

Imports of these products are currently classifiable under the following Harmonized Tariff Schedule (HTS) subheadings: 7306.30.10.00, 7306.30.50.25, 7306.30.50.32, 7306.30.50.40, 7306.30.50.55, 7306.30.50.85, and 7306.30.50.90. Although the HTS subheadings are provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

Period of Investigation

The period of investigation (POI) is April 1, 1991, through September 30, 1991.

Such or Similar Comparisons

We have determined that all the products covered by this investigation constitute a single category of such or similar merchandise.

Fair Value Comparisons

To determine whether sales of standard pipe from Taiwan to the United States were made at less than fair value, we compared the United States price (USP) to the foreign market value (FMV), as specified in the "United States Price" and "Foreign Market Value" sections of this notice. We used BIA as required by section 776(c) of the Act because respondents' questionnaire responses as of March 31, 1992, were inadequate. Chief among the substantive deficiencies for both companies were improperly encoded, and therefore unexaminable, sales databases.

We determine that the best information available was information submitted in the petition.

Since KHC has attempted to cooperate with the Department's investigation, we have determined BIA to be the average of margins calculated based on information in the petition. We will consider KHC's questionnaire responses for purposes of making our final determination if it remedied the deficiencies with its submission of April 14, 1992.

Yieh Hsing, having failed to respond to the Department's second deficiency letter by the April 14, 1992, deadline, is an uncooperative respondent. Accordingly, we have determined BIA to be the highest of the margins calculated based on information in the petition.

United States Price

We based USP on information provided in the petition. Petitioner provided U.S. prices based on (1) the resale price in the United States as quoted by service centers and importers; and (2) the average customs value for standard pipe over 114.3 millimeters in outside diameter and over 1.655 millimeters in wall thickness for the second quarter of 1991. The resale prices were adjusted by the petitioners for freight, distributor mark-up, import duties, port fees, and brokerage and handling charges to arrive at ex-factory prices.

Foreign Market Value

We based FMV on information provided in the petition. Petitioner based FMV on price quotations for various sizes and finishes of black standard pipe obtained from one producer of subject merchandise. We converted the prices using the exchange rate effective on the date of the U.S. price quotation.

Currency Conversion

We made currency conversions based on the official exchange rates in effect on the dates of the U.S. price quotations as certified by the Federal Reserve Bank.

Verification

As provided in section 776(b) of the Act, we will verify the information that we determine is acceptable for use in making our final determination.

Suspension of Liquidation

In accordance with section 733(d)(1) of the Act, we are directing the Customs Service to suspend liquidation of all entries of standard pipe from Taiwan that are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. The Customs Service shall require a cash deposit or posting of a bond equal to the estimated preliminary dumping margins, as shown below. This suspension of liquidation will remain in effect until further notice. The LTFV margins are as follows:

Producer/manufacturer/exporter	Weighted-average margin percentage
Kao Hsing Chang Iron & Steel Corp	19.46
Yieh Hsing Enterprise Co., Ltd	27.65
All Others	23.56

ITC Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our determination. If our final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after our final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Public Comment

In accordance with 19 CFR 353.38, case briefs or other written comments in at least ten copies must be submitted to the Assistant Secretary for Import Administration no later than June 2, 1992, and for rebuttal briefs no later than June 9, 1992. In accordance with 19 CFR 353.38(b), we will hold a public hearing, if requested, to afford interested parties an opportunity to comment on arguments raised in case or rebuttal briefs. Tentatively, the hearing will be held on June 11, 1992, at 2 p.m. at the U.S. Department of Commerce, room 1851, 14th Street and Constitution Avenue, NW., Washington, DC 20230. Parties should confirm by telephone the time, date, and place of the hearing 48 hours before the scheduled time.

Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce, room B-099, within ten days of the publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. In accordance with 19 CFR 353.38(b), oral presentations will be limited to issues raised in the briefs.

If this investigation proceeds normally, we will make our final determination by July 6, 1992.

This determination is published pursuant to section 733(f) of the Act and 19 CFR 353.15(a)(4).

Dated: April 21, 1992.

Alan M. Dunn,

Assistant Secretary for Import Administration.

[FR Doc. 92-9885 Filed 4-27-92; 8:45 am]

BILLING CODE 3510-DS-M

[A-307-805]

Preliminary Determination of Sales at Less Than Fair Value: Circular Welded Non-Alloy Steel Pipe From Venezuela

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: April 28, 1992.

FOR FURTHER INFORMATION CONTACT: Judith Wey or David J. Goldberger, Office of Antidumping Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 377-8320, or (202) 377-4136, respectively.

PRELIMINARY DETERMINATION: We preliminarily determine that imports of circular welded non-alloy steel pipe ("standard pipe") from Venezuela are being, or are likely to be, sold in the United States at less than fair value (LTFV), as provided in section 733 of the Tariff Act of 1930, as amended (the Act). Because respondent failed to provide adequate information in a timely manner, we have based our preliminary LTFV calculations on the best information otherwise available (BIA).

In this instance, we have determined the BIA to be the average of the margins that resulted from the fair value comparisons provided in the petition for the respondent in this investigation. The estimated margins are shown in the *Suspension of Liquidation* section of this notice.

Case History

Since the initiation of this investigation on October 15, 1991, (56 FR 52528, October 21, 1991), the following events have occurred.

On November 8, 1991, the U.S. International Trade Commission (ITC) issued an affirmative preliminary injury determination.

On November 27, 1991, the Department presented an antidumping duty questionnaire to C.A. Conduven (Conduven). Conduven accounted for at least 60 percent of the exports of the subject merchandise to the United States.

Conduven submitted questionnaire responses in December 1991 and January 1992. On February 4, 1992, petitioners requested that the Department postpone the preliminary determination to April 21, 1992, pursuant to 19 CFR 353.15(c). The Department granted this request on February 10, 1992. (57 FR 5997, February 19, 1992).

We issued a supplemental questionnaire on February 27, 1992, citing significant deficiencies in Conduven's response. In a meeting on February 28, 1992, we informed counsel for Conduven that the major deficiencies in Conduven's responses had to be addressed, or we would be unable to use its information in making our preliminary determination. On March 16, 1992, we received the deficiency response from Conduven.

On April 13, 1992, eight days prior to the preliminary determination in this investigation, Conduven filed an additional supplemental response, with new computer tapes, in an attempt to correct numerous deficiencies and errors it had discovered in its earlier responses. This submission contained significant revisions to the information already on the record, including the addition of several charges and adjustments not previously presented and the recalculation of several existing charges and adjustments. (See April 14, 1992, Memorandum from Gary Taverman, Director, Division I, to Francis J. Sailer, Deputy Assistant Secretary for Investigations, outlining the deficiencies in Conduven's responses.) Because of the magnitude of the errors in Conduven's earlier submissions made apparent by the presentation of significant new information one week prior to the preliminary determination, we have based Conduven's preliminary LTFV calculations on BIA. We will consider Conduven's most recently revised questionnaire response for our final determination.

Scope of Investigation

The merchandise subject to this investigation is circular welded non-alloy steel pipes and tubes, of circular cross-section, not more than 406.4mm (16 inches) in outside diameter, regardless of wall thickness, surface finish (black, galvanized, or painted), or end finish (plain end, bevelled end, threaded, or threaded and coupled). These pipes and tubes are generally known as standard pipe, though they may also be called structural or mechanical tubing in certain applications. Standard pipes and tubes are intended for the low pressure conveyance of water, steam, natural gas, air, and other liquids and gases in plumbing and heating systems, air conditioning units, automatic sprinkler systems, and other related uses. Standard pipe may also be used for light load-bearing and mechanical applications, such as for fence tubing, and for protection of electrical wiring, such as conduit shells.

The scope is not limited to standard pipe and fence tubing, or those types of mechanical and structural pipe that are used in standard pipe applications. All carbon steel pipes and tubes within the physical description outlined above are included within the scope of this investigation, except line pipe, oil country tubular goods, boiler tubing, cold-drawn or cold-rolled mechanical tubing, pipe and tube hollows for redraws, finished scaffolding, and finished rigid conduit. Standard pipe that is dual or triple certified/stenciled that enters the U.S. as line pipe of a kind used for oil or gas pipelines is also not included in this investigation.

Imports of these products are currently classifiable under the following Harmonized Tariff Schedule (HTS) subheadings: 7306.30.10.00, 7306.30.50.25, 7306.30.50.32, 7306.30.50.40, 7306.30.50.55, 7306.30.50.85, and 7306.30.50.90. Although the HTS subheadings are provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

Period of Investigation

The period of investigation (POI) is April 1, 1991, through September 30, 1991.

Such or Similar Comparisons

We have determined that all the products covered by this investigation constitute a single category of such or similar merchandise.

Fair Value Comparisons

To determine whether sales of standard pipe from Venezuela to the United States were made at less than fair value, we compared the United States price (USP) to the foreign market value (FMV), as specified in the "United States Price" and "Foreign Market Value" sections of this notice. As mentioned above, we used BIA as required by section 776(c) of the Act because Conduven did not provide adequate information in a timely manner for purposes of the preliminary determination. We determined that BIA was information submitted in the petition.

United States Price

We based USP on information provided in the petition. Petitioners provided U.S. prices based on the average customs value of imported standard pipe during the second quarter of 1991.

Foreign Market Value

We based FMV on information provided in the petition. Petitioners based FMV on actual home market price quotations from Venezuelan producers of standard pipe and from retail sellers of standard pipe in Venezuela. The petitioners adjusted, where appropriate, for quantity discounts, cash discounts, and distributor and retailer mark-ups.

Currency Conversion

No certified rates of exchange, as furnished by the Federal Reserve Bank of New York, were available for Venezuela for the POI. In place of the official certified rates, we used the average quarterly exchange rates published by the International Monetary Fund.

Verification

As provided in section 776(b) of the Act, we will verify the information that we determine is acceptable for use in making our final determination.

Suspension of Liquidation

In accordance with section 733(d)(1) of the Act, we are directing the Customs Service to suspend liquidation of all entries of standard pipe from Venezuela that are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. The Customs

Service shall require a cash deposit or posting of a bond equal to the estimated preliminary dumping margins, as shown below. This suspension of liquidation will remain in effect until further notice.

Producer/manufacturer/exporter	Weighted-average margin percentage
C.A. Conduven	32.29
All others	32.29

ITC Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our determination. If our final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after our final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Public Comment

In accordance with 19 CFR 353.38, case briefs or other written comments in at least ten copies must be submitted to the Assistant Secretary for Import Administration no later than June 3, 1992, and for rebuttal briefs no later than June 10, 1992. In accordance with 19 CFR 353.38(b), we will hold a public hearing, if requested, to afford interested parties an opportunity to comment on arguments raised in case or rebuttal briefs. Tentatively, the hearing will be held on June 12, 1992, at 9:30 a.m. at the U.S. Department of Commerce, room 1852, 14th Street and Constitution Avenue, NW., Washington, DC 20230. Parties should confirm by telephone the time, date, and place of the hearing 48 hours before the scheduled time.

Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce, room B-099, within ten days of the publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issue to be discussed. In accordance with 19 CFR 353.38(b), oral presentations will be limited to issues raised in the briefs.

This determination is published pursuant to section 733(f) of the Act and 19 CFR 353.15(a)(4).

Dated: April 21, 1992.

Alan M. Dunn,

Assistant Secretary for Import Administration.

[FR Doc. 92-9884 Filed 4-27-92; 8:45 am]

BILLING CODE 3510-DS-M

National Oceanic and Atmospheric Administration

National Marine Fisheries Service; Endangered Species; Application for Scientific Research Permit; Robert van Dam, Physiological Research Laboratory, Scripps Institution of Oceanography, University of California (P509)

Notice is hereby given that an applicant has applied in due form for a Scientific Research Permit to take an endangered species as authorized by the Endangered Species Act of 1973 (16 U.S.C. 1531-1543) and the National Marine Fisheries Service (NMFS) regulations governing endangered fish and wildlife permits (50 CFR part 217-222).

1. *Applicant:* Robert van Dam, Physiological Research Laboratory, Scripps Institution of Oceanography, University of California, San Diego, La Jolla, California 92093-0204.

2. *Type of Permit:* Scientific Research.

3. *Name and Number of Species:* 40 Hawksbill Sea Turtles, *Eretmochelys imbricata.*

4. *Type of Take:* The applicant proposes to investigate the ecological role of juvenile and subadult hawksbills in the reef environment. Research emphasis is on the foraging characteristics of these animals. Specifically, it is the objective to determine: (1) What items are consumed by the turtles, (2) the abundance and distribution of those food items, and (3) the patterns of turtle behavior associated with feeding. A maximum of 40 juvenile and subadult hawksbill turtles will be caught and their stomach contents sampled to investigate differences in foraging patterns.

5. *Location and Duration of Activity:* The applicant requests a permit for the period of 1 June 1992 through 30 November 1992. All of the research activities during this period will take place at Mona Island, Puerto Rico.

Written data or views, or requests for a public hearing on this application should be submitted to the NMFS, U.S. Department of Commerce, 1335 East-West Highway, Silver Spring, Maryland 20910, within 30 days of the publication of this notice. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular application would be appropriate. The holding of such a hearing is at the discretion of the Assistant Administrator for Fisheries. All statements and opinions contained in this application are summaries of those of the applicant and do not necessarily reflect the views of the NMFS.

Documents submitted in connection with the above application are available for review by interested persons in the following offices:

Office of Protected Resources, NMFS, NOAA, 1335 East-West Highway, SSMC #1, room 8268, Silver Spring, Maryland 20910, (301/713-2289); and Director, Southeast Region, NOAA, National Marine Fisheries Service, 9450 Koger Boulevard, St. Petersburg, Florida 33702.

Dated: April 22, 1992.

Nancy Foster,

Director, Office of Protected Resources.

[FR Doc. 92-9878 Filed 4-27-92; 8:45 am]

BILLING CODE 3510-22-M

Marine Mammals

AGENCY: National Marine Fisheries Service, NOAA, Commerce.

ACTION: Request for Modification to Scientific Research Permit No. 598 (P77#28).

Notice is hereby given that the Alaska Fisheries Science Center, National Marine Mammal Laboratory, National Marine Fisheries Service, 7600 Sand Point Way NE., Bin C15700, Seattle, WA 98115-0070, has requested a modification to Permit No. 598 pursuant to the provisions of § 216.33 (d) and (e) of the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR Part 216).

Permit No. 598 issued on July 23, 1988 (52 FR 27697) authorized a total of 32,500 northern fur seal pups (*Callorhinus ursinus*) to be taken annually for population monitoring and assessment programs. The research involved capturing, restraint to affix radio transmitters, time-depth recorders, satellite-linked instruments, swim speed recorders, and/or other environmental sensors and behavioral recorders, lavaging or enema samples taken, and release of the animal.

Four previous modifications to this permit have been requested. Modification No. 1 authorized up to 80 northern fur seals per year to be incidentally killed or injured during authorized research activities, and an additional 3,260 northern fur seals were authorized to be taken annually to allow continuation of essential population

monitoring and assessment programs by specified methods. Modification No. 2 authorized up to 30,000 juvenile male northern fur seals to be taken annually by roundup of which up to 3,900 were authorized to be captured by physical restraint, marked, handled and released annually and the rates of survival monitored. Modification No. 3 authorized the use of Telazol (1.2—1.5 mg/kg) to chemically restrain seals rather than physically restrain large adult males too large to be handled safely during the attachment of satellite tags and the removal of entangling debris. Modification No. 4 authorized up to 81 additional fur seals to be harassed, captured, handled, released, encircled, instrumented and recaptured.

A new modification has now been requested to take up to 600 northern fur seals (*Callorhinus ursinus*) in the following manner: (a) A total of 100 seals (50 female/pup pairs) will be marked with hair bleach; (b) vocalizations of mother/pup pairs will be recorded for playback experiments; (c) 100 adult females will be tagged; and (d) 400 will be incidentally harassed while conducting these activities. Taking is requested from June-August 1992 on the Pribilof Islands.

Written data or views, or requests for a public hearing on this proposed modification, should be submitted to the Assistant Administrator for Fisheries, National Marine Fisheries Service, U.S. Department of Commerce, 1335 East-West Highway, Room 7324, Silver Spring, MD 20910, within 30 days of the publication date of this notice. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular proposal would be appropriate. The holding of such a hearing is at the discretion of the Assistant Administrator for Fisheries. All statements and opinions contained in this proposed modification are summaries of those of the applicant and do not necessarily reflect the views of the National Marine Fisheries Service.

Documents submitted in connection with the Permit and Modifications are available for review, by appointment, in the Permits Division, Office of Protected Resources, National Marine Fisheries Service, 1335 East-West Highway, room 7324, Silver Spring, MD 20910 (301/713-2289);

Director, Alaska Region, National Marine Fisheries Service, NOAA, 709 West 9th Street, Federal Bldg., Juneau, AK 99802 (907/586-7221);

Director, Northwest Region, National Marine Fisheries Service, NOAA, 7600 Sand Point Way, NE., BIN C15700, Seattle, WA 98115-0070 (206/526-6150); and Director, Southwest Region, National Marine Fisheries Service, NOAA, 501 W. Ocean Blvd., Long Beach, California 90802-4213 (310/980-4015).

Dated: April 22, 1992.

Nancy Foster,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 92-9879 Filed 4-27-92; 8:45 am]

BILLING CODE 3510-22-M

National Technical Information Service

Advisory Board; Open Meeting

SUMMARY: The Advisory Board was established by statute (Pub. L. 100-519) on October 24, 1988, and received its charter on September 15, 1989. Its function is to advise the Secretary of Commerce and the Director of the National Technical Information Service on the general policies and operations of the National Technical Information Service (NTIS), including policies in connection with fees and charges for its services.

TIME AND PLACE: May 14, 1992, from 9 a.m. to 5 p.m.; and May 15, 1992, from 9 a.m. to 5 p.m. The meeting will take place at the National Technical Information Service, 8001 Forbes Place, suite 210A, Springfield, Virginia 22161.

DRAFT AGENDA:

Thursday, May 14, 1992

9:00—Opening, William W. Carpenter, Chairman.

Welcome, Donald R. Johnson, Acting Director.

Adoption of the Agenda, William W. Carpenter, Chairman.

Adoption of the Report of the 5th Meeting.

9:30—Progress Report and Update, Donald R. Johnson.

10:30—Break

10:45—Modernization and Equipment, J. Thomas Walker, Alan R. Wenberg.

12:00—Lunch.

1:30—The American Technology Preeminence Joseph E. Clark Act and Related Issues.

Public Participation.

Break.

3:00—Closed Session.

5:00—Adjournment.

Friday, May 15, 1992

9:00—Related Government Programs, Donald R. Johnson.

10:00—Break.

10:15—New Product Reviews.

Public Participation.

11:30—Lunch

1:00—NTIS Area: Sales and Customer Service Tour; Demonstration of Training for Sales Representatives/Document Shipping, David B. Francis.

Break.

3:00—Board Advice and Recommendation, William W. Carpenter.

Public Participation.

4:00—Closing, William W. Carpenter.

Chairman's Summary.

Planning for Future Meetings.

Adjurnment.

PUBLIC PARTICIPATION: The meeting will be open to public participation. Approximately thirty minutes each day will be set aside for oral comments or questions as indicated in the agenda. Seats will be available for the public and for the media. Seats will be available on a first-come, first-served basis. Any member of the public may submit written comments concerning the Board's affairs at any time before and after the meeting. Copies of the minutes of the meeting will be available within thirty days from the address given below.

FOR FURTHER INFORMATION CONTACT: Dorothy Aukofer MacEoin, Executive Secretary, NTIS Advisory Board, National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161. Telephone: 703-487-4779; by fax 703-487-4009.

Dated: April 21, 1992.

Donald R. Johnson,

Acting Director, National Technical Information Service.

[FR Doc. 92-9751 Filed 4-27-92; 8:45 am]

BILLING CODE 3510-04-M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Additional Information on Amendment of Export License/Visa Requirements to Require Manufacturer's Identification (M.I.D.) on the Export Document

April 23, 1992.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Additional information on amending export license/visa requirements to require manufacturer s identification.

EFFECTIVE DATE: May 1, 1992.

FOR FURTHER INFORMATION CONTACT: Janet Heinzen, International Trade Specialist, Office of Textiles and

Apparel, U.S. Department of Commerce, (202) 377–4212.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

Notices published in the **Federal Register** on April 10, 1992 (57 FR 12478); April 14, 1992 (57 FR 12912); and April 17, 1992 (57 FR 13710), respectively, announced an amendment to export license/visa requirements for textile products, produced or manufactured in the People's Republic of China, Jamaica and Hungary and exported from these countries on and after May 1, 1992.

In response to a number of inquiries, additional information is being provided on this new requirement. The name and address of the company should be placed somewhere on the front of the original export license/visa document, not within the circular visa stamp. It should be preceded by the label "manufacturer's identification" or "M.I.D." The name is the full name of the company which performs the substantial part of the manufacturing of the product. The address should include the street name or P.O. Box number (if available), and the city and/or province where the manufacturing occurs. In the case of a shipment covered by a single export license/visa document containing products which are each manufactured by a number of different companies, the name and address of each company involved should be listed on the export license/visa document. If additional space is needed for listing the name and address of the firms, the back of the export license/visa document may be used. In cases where 9802.00.80 operations are involved, the actual foreign assembler should be identified as the manufacturer. Responsible officials will make their best efforts to determine the name and address of a firm or firms which best meet the basic criterion of being an actual manufacturer of the product. This information should appear on the export license/visa document prior to export from the country of manufacture. However, for goods exported during the period May 1, 1992 through May 31, 1992, the importer may type this required information on the front of the original export license/visa document. For goods exported on or after June 1, 1992 without the M.I.D. on the export license/visa document, a new visa or replacement visa containing this information must be obtained.

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

April 23, 1992.

Commissioner of Customs,
Department of the Treasury, Washington DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directives issued to you on April 6, April 8 and April 13, 1992, by the Chairman, Committee for the Implementation of Textile Agreements. Those directives amend the visa requirements for textile products, produced or manufactured in the People's Republic of China, Jamaica and Hungary, respectively, to require identification of the manufacturer of the textile product covered by the visa.

Effective on May 1, 1992, for goods produced or manufactured in China, Jamaica and Hungary and exported on and after May 1, 1992, you are directed to require that the complete name and address of the company actually involved in the manufacturing process of the textile product be placed on the export license/visa document prior to exportation. However, for goods exported during the period May 1, 1992 through May 31, 1992, the importer may type this required information on the front of the original export license/visa document. For goods exported on and after June 1, 1992, this information must be placed on the export document prior to export to the United States. For goods exported without the manufacturer's identification (M.I.D.) on the export license/visa document, a new visa or replacement visa containing this information must be obtained.

Also, in cases involving 9802.00.80 operations, the actual foreign assembler should be identified as the manufacturer.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 92–9803 Filed 4–27–92; 8:45 am]

BILLING CODE 3510–DR–F

Elimination of a Sublimit for Certain Cotton Textile Products Produced or Manufactured in Sri Lanka

April 23, 1992.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs eliminating a sublimit.

EFFECTIVE DATE: April 30, 1992.

FOR FURTHER INFORMATION CONTACT: Kim-Bang Nguyen, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377–4212. For quota status information, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 343–6580. For information on embargoes and quota re-openings, call (202) 377–3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The current sublimit for Categories 338–S/339–S is being eliminated.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 56 FR 60101, published on November 27, 1991). Also see 56 FR 29232, published on June 26, 1991.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the bilateral agreement, but are designed to assist only in the implementation of certain of its provisions.

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

April 23, 1992.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on June 21, 1991, by the Acting Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool and man-made fiber textile products and silk blend and other vegetable fiber apparel, produced or manufactured in Sri Lanka and exported during the twelve-month period which began on July 1, 1991 and extends through June 30, 1992.

Effective on April 30, 1992, you are directed to amend further the directive dated June 21, 1991 to eliminate the sublimit for Categories 338–S/339–S [1]. Import charges made to the

[1] Category 338–S: only HTS numbers 6103.22.0050, 6105.10.0010, 6105.10.0030, 6105.90.3010, 6109.10.0027, 6110.20.1025, 6110.20.2040, 6110.20.2065, 6110.90.0068, 6112.11.0030 and 6114.20.0005; Category 339–S: only HTS numbers 6104.22.0060, 6104.29.2049, 6106.10.0010, 6106.10.0030, 6106.90.2010, 6106.90.3010, 6109.10.0070, 6110.20.1030, 6110.20.2045, 6110.20.2075, 6110.90.0070, 6112.11.0040, 6114.20.0010 and 6117.90.0022.

sublimit shall be retained and shall remain charged to the current level for Categories 338/339.

The Committee for the Implementation of Textile Agreements has determined that this action falls within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 92-9802 Filed 4-27-92; 8:45 am]

BILLING CODE 3510-DR-F

DEPARTMENT OF EDUCATION

Fund for the Improvement and Reform of Schools and Teaching; Board Meeting

AGENCY: Fund for the Improvement and Reform of Schools and Teaching Board, Education.

ACTION: Notice of a partially closed meeting.

SUMMARY: This notice sets forth the schedule and agenda of a partially closed meeting of the Fund for the Improvement and Reform of Schools and Teaching Board. This Notice also describes the functions of the Board. Notice of this meeting is required under section 10(a)(2) of the Federal Advisory Committee Act.

DATES AND TIMES: May 11, 1992, 9 a.m.–5 p.m. (closed); May 12, 1992, 9 a.m.–11:30 a.m. (closed); May 12, 1992, 12 p.m.–1 p.m. (open); May 12, 1992, 1 p.m.–3 p.m. (closed); May 13, 1993, 9 a.m.–3 p.m. (open).

ADDRESSES: Quality Hotel, Capitol Hill, Lobby Conference Room, 415 New Jersey Avenue, NW., Washington, DC on May 11, 9 a.m.–5 p.m.; May 12, 1992, 9 a.m.–11:30 a.m.; and, May 13, 9 a.m. to 3 p.m. Holiday Inn, The Governor's House, Rhode Island Avenue at 17th Street, NW., Washington, DC on May 12, 12 p.m.–3 p.m.

FOR FURTHER INFORMATION CONTACT: Diane Hill, Fund for the Improvement and Reform of Schools and Teaching, U.S. Department of Education, 555 New Jersey Avenue, NW., room 522, Washington, DC 20208-5524, (202) 219-1496.

SUPPLEMENTARY INFORMATION: The Fund for the Improvement and Reform of Schools and Teaching (FIRST) Board was established under Section 3231 of the Hawkins-Stafford Elementary and Secondary School Improvement Amendments of 1988 (Pub. L. 100-297).

The Board was established to advise the Secretary concerning developments in education that merit his attention; identify promising initiatives to be supported under the authorizing legislation; and advise the Secretary and the Director of FIRST on the selection of projects under consideration for support, and on planning documents, guidelines and procedures for grant competitions carried out by FIRST.

The FIRST Board Meeting will be closed to the public on May 11, from 9 a.m. to 5 p.m. for the Board to read and discuss the Schools and Teachers Program, Schools and Teachers—School Level Program, and Family-School Partnership Program applications submitted for funding. The meeting will also be closed on May 12, from 9 a.m. to 11:30 a.m. and again from 1 p.m. to 3 p.m. when the FIRST Board and the Fund for the Improvement and Reform of Postsecondary Education (FIPSE) Board will read and discuss the Schools and Teachers Program, CFDA number: 84.211C applications submitted for funding. This portion of the meeting is closed under the authority of section 10(d) of the Federal Advisory Committee Act (Pub. L. 92-463; 5 U.S.C.A. appendix 2) and under exemptions (4) and (6) of the Government in the Sunshine Act (Pub. L. 94-409; 5 U.S.C. 552b(c) (4 and 6)). The review and discussions during the closed portions of the meetings will involve applicants, funding requests and levels, and names and comments of expert reviewers which would likely disclose commercial or financial information obtained from a person and privileged or confidential, or would disclose information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy if conducted in open session. Such matters are protected by exemptions (4) and (6) of section 552b of title 5 U.S.C.

A summary of the activities at the closed sessions and related matters which are informative to the public consistent with the policy of title 5 U.S.C. 552b(c) will be available to the public within fourteen days of the meeting.

The meeting is open to the public on Tuesday, May 12, from 12 p.m. to 1 p.m. The FIRST Board will meet with the FIPSE Board to coordinate the work of the Fund with the work of FIPSE as directed by FIRST legislation. The meeting will be open to the public on May 13 from 9 a.m. to 3 p.m. The agenda for the open portion of the meeting will include approval of the minutes from the February meeting and a discussion on the Board's recommended 1993 priorities. The meeting will conclude with a discussion of the upcoming agenda for and date of the next Board meeting.

Records are kept of all Board proceedings, and are available for public inspection at the office of the Fund for the Improvement and Reform of Schools and Teaching, U.S. Department of Education, 555 New Jersey Avenue, NW., room 522, Washington, DC 20208-5524, from the hours of 8:30 a.m. to 5 p.m.

Dated: April 23, 1992.

Diane Ravitch,

Assistant Secretary for Educational Research and Improvement.

[FR Doc. 92-9819 Filed 4-24-92; 8:45 am]

BILLING CODE 4000-01-M

National Education Commission on Time and Learning; Meeting

AGENCY: National Education Commission on Time and Learning, Education.

ACTION: Notice of partially closed meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a partially closed meeting of the National Education Commission on Time and Learning. This notice also describes the functions of the Commission. Notice of this meeting is required under section 10(a)(2) of the Federal Advisory Committee Act.

DATE AND TIME: May 15, 1992 from 9 a.m. to 4 p.m..

ADDRESS: Vista Hotel, Ashlawn Room, 1400 M Street, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Julia Anna Anderson, Special Assistant, 555 New Jersey Ave., Capitol Place Room 610B, Washington, DC 20208. Telephone: (202) 219-2249.

SUPPLEMENTARY INFORMATION: The National Education Commission on Time and Learning is established under section 102 of the Education Council Act of 1991 (20 U.S.C. 1221-1). The Commission is established to examine the quality and adequacy of the study and learning time of elementary and secondary students in the United States, including issues regarding the length of the school day and year, the extent and role of homework, how time is being used for academic subjects, year-round professional opportunities for teachers, and the use of school facilities for extended learning program.

During the morning portion of the meeting from 9 a.m. to 12 noon, the Commission meeting will be closed to the general public to review applications for the position of Executive Director of the Commission. This portion of the meeting will be closed under the

authority of section 10(d) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. appendix 2) and under exemptions (2) and (6) of Section 552b of the Government in the Sunshine Act (Pub. L. 94–409; 5 U.S.C. 552b). The review and subsequent discussion of the applicants resumes and qualifications relates solely to the internal personnel rules and practices of an agency and would disclose information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy if conducted in open session. Such matters are protected by exemptions (2) and (6) of section 552b(c) of title 5 U.S.C.

The meeting will be open to the public from 1:30 p.m. to 4 p.m. The proposed agenda for the afternoon session includes: discussion of the mandates of the Commission and the Commissioners philosophy and expectations of elementary and secondary education and the Commission's role.

A summary of the activities at the closed session and related matters which are informative to the public consistent with the policy of title 5 U.S.C. 522b(c) will be available to the public within fourteen days of the meeting.

Records are kept of all Commission proceedings at the Office of the National Education Commission on Time and Learning, 555 New Jersey Ave., NW., room 610B, Washington, DC 20208 from the hours of 9 a.m. to 5:30 p.m.

Dated: April 20, 1992.

Diane Ravitch,

Assistant Secretary, OERI.

[FR Doc. 92–9808 Filed 4–27–92; 8:45 am]

BILLING CODE 4000–01–M

National Board of the Fund for the Improvement of Postsecondary Education, Meeting.

AGENCY: National Board of the Fund for the Improvement of Postsecondary Education, Education.

ACTION: Notice of partially closed meeting.

SUMMARY: This notice sets forth the proposed agenda of a forthcoming meeting of the National Board of the Fund for the Improvement of Postsecondary Education. This notice also describes the functions of the Board. Notice of this meeting is required under section 10 (a)(2) of the Federal Advisory Committee Act.

DATES AND TIMES: May 11, 1992 from 9 a.m. to 5 p.m. (closed); May 12, 1992 from 9 a.m. to 12 p.m. (closed), 12 p.m. to 1 p.m. (open), 1 p.m. to 3 p.m. (closed), 3 to 5 (open); and May 13, 1992 from 9 a.m. to 12 p.m. (closed), 12 p.m. to 5 (open).

ADDRESSES: Governor's House Holiday Inn, Rhode Island Avenue at 17th Street, NW., Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Charles Karelis, Director, Fund for the Improvement of Postsecondary Education, 7th & D Streets, SW., Washington, DC 20202. Telephone: (202) 708–5750.

SUPPLEMENTARY INFORMATION: The National Board of the Fund for the Improvement of Postsecondary Education (Fund) is established under section 1003 of the Higher Education Act of 1965, as amended (20 U.S.C. 1135a–1). The National Board of the Fund is authorized to recommend to the Director of the Fund and the Assistant Secretary for Postsecondary Education priorities for funding and approval or disapproval of grants submitted to the Fund.

On May 12, 1992 from 12 p.m. to 1 p.m. and 3 p.m. to 5 p.m., and on May 13 from 12 p.m. to 5 p.m. the Board will meet in open session. The proposed agenda for the open portion of the meeting will include a review of the progress on FIPSE special initiatives, including: The 21st Century Committee; policy of the Leadership Projects in Science and the Humanities program; Comprehensive Program revisions; and ethics review for new Board members.

On May 11, 1992 from 9 a.m. to 5 p.m., and May 13, 1992 from 9 a.m. to 12 p.m., the meeting will be closed to the public for purpose of reviewing and evaluating grant applications submitted to the Fund under the Comprehensive Program. On May 12, 1992 from 9 a.m. to 12 p.m. the meeting will be closed to the public for the purpose of discussing grant applications submitted to the Fund under the College-School Partnerships to Improve Learning of Essential Academic Subjects, Kindergarten Through College program. On May 12, 1992 from 1 p.m. to 3 p.m., the meeting will be closed to the public for the purpose of jointly meeting with the Fund for the Improvement and Reform of Schools and Teaching (FIRST) National Board to review and evaluate grant applications under the College-School Partnerships to Improve Learning of Essential Academic Subjects, Kindergarten Through College Program. This portion of the meeting will be closed under the authority of section 10(d) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C.A. appendix 2) and under exemptions (4) and (6) of the Government in the Sunshine Act (Pub. L. 94–409, 5 U.S.C. 552b(c)(4) and (6). The review and discussions of the applications and the qualifications of proposed staff to work on these grants is likely to disclose commercial or financial information obtained from a person and privileged or confidential, or information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy if conducted in open session.

A summary of the activities at the closed session and related matters which are informative to the public consistent with the policy of title 5 U.S.C. 552b will be available to the public within fourteen days of the meeting.

Records are kept of all Board proceedings, and are available for public inspection at the Office of the Fund for the Improvement of Postsecondary Education, room 3100, Regional Office Building #3, 7th & D Streets, SW., Washington, DC 20202 from the hours of 8 a.m. to 4:30 p.m.

Carolynn Reid-Wallace,

Assistant Secretary for Postsecondary Education.

[FR Doc. 92–9748 Filed 4–27–92; 8:45 am].

BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. JD92–05906T, New Mexico-32]

State of New Mexico; NGPA Notice of Determination by Jurisdictional Agency Designating Tight Formation

April 22, 1992.

Take notice that on April 20, 1992, the Oil Conservation Division of the New Mexico Department of Energy, Minerals and Natural Resources (New Mexico), submitted the above-referenced notice of determination pursuant to § 271.703(c)(3) of the Commission's regulations, that a portion of the Dakota Formation in Rio Arriba, County, New Mexico, qualifies as a tight formation under section 107(b) of the Natural Gas Policy Act of 1978. The area of application is described on the attached appendix.

The notice of determination also contains New Mexico's and the Bureau of Land Management's findings that the referenced portion of the Dakota Formation meets the requirements of the Commission's regulations set forth in 18 CFR part 271.

The application for determination is available for inspection, except for material which is confidential under 18 CFR 275.206, at the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC

20426. Persons objecting to the determination may file a protest, in accordance with 18 CFR 275.203 and 275.204, within 20 days after the date this notice is issued by the Commission.

Lois D. Cashell,

Secretary.

Appendix

Rio Arriba County, New Mexico

Township 26 North, Range 6 West, NMPM
Section 6: All
Township 26 North, Range 7 West, NMPM
Sections 1 and 2: All
Sections 11 and 12: All
Township 27 North, Range 6 West, NMPM
Sections 16 through 23: All
Sections 26 through 32: All
Township 27 North, Range 7 West, NMPM
Sections 13 and 14: All
Section 15: E/2
Sections 22: E/2
Sectionss 23 through 26: All
Section 27: NE/4 S/2
Section 28: S/2
Sections 33 through 36: All.

The area of application contains 20,624.7 acres, more or less, of federal, state and fee lands.

[FR Doc. 92-9837 Filed 4-27-92; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TA91-1-48-003]

ANR Pipeline Co.; Proposed Changes in FERC Gas Tariff

April 22, 1992.

Take notice that ANR Pipeline Company ("ANR"), on April 16, 1992, tendered for filing as part of its Original Volume Nos. 1 and 1-A of its FERC Gas Tariff, an original and five copies of the following tariff sheets:

Original Volume No. 1

Fourth Revised Sheet No. 77
Original Sheet No. 77A
Fourth Revised Sheet No. 78

ANR states that the subject tariff sheets are being submitted to comply with the Commission's March 19, 1992, "Order Accepting Tariff Filing, With Modifications, And Terminating Technical Conference" in the above referenced proceedings.

ANR states that all of its Volume No. 1 customers and interested state commissions have been apprised of this filing via U.S. Mail.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before April 29, 1992. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 92-9838 Filed 4-27-92; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER92-437-000]

Central Vermont Public Service Corp., Notice of Filing

April 22, 1992.

Take notice that on April 6, 1992, Central Vermont Public Service Corporation tendered for filing a notice of cancellation of service to three of its customers: the Village of Orleans Electric, the Village of Enosburg Falls Water and Light Department, and Barton Village, Inc.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions to protests should be filed on or before May 1, 1992. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 92-9780 Filed 4-27-92; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP92-154-000]

Colorado Interstate Gas Co.; Proposed Changes in FERC Gas Tariff

April 22, 1992.

Take notice That Colorado Interstate Gas Company ("CIG"), on April 16, 1992, tendered for filing the following tariff sheet to revise its FERC Gas Tariff, Original Volume No. 1:

Original Sheet No. 61G11.3

CIG states that the above-referenced tariff sheet is being filed to implement recovery of Buyout-Buydown costs incurred by CIG as a result of the settlement of contract claims in conformance with the procedures reflected in the Commission's Order Nos. 528 and 528-A.

CIG states that, pursuant to the provisions of Order Nos. 528 and 528-A, CIG will allocate its Buyout-Buydown costs between its jurisdictional and nonjurisdictional customers, absorb 50 percent of the jurisdictional portion of the Buyout-Buydown costs, and recover 50 percent of such costs through fixed surcharges applicable to its jurisdictional firm sales customers. CIG states that the total and the jurisdictional portion of the Buyout-Buydown costs related to this filing are $1,721,487 and $1,714,133, respectively. Therefore, CIG is proposing to recover $57,066 from its affected jurisditional firm sales customers.

CIG has requested that the Commission accept this filing, to become effective May 10, 1992.

CIG states that copies of the filing were served upon all of its affected firm sales customers and interested State Commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with §§ 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before April 29, 1992. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 92-9839 Filed 4-27-92; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP91-181-004]

Northern Natural Gas Co.; Proposed Changes in FERC Gas Tariff

April 22, 1992.

Take notice that, in compliance with the Commission's Order dated April 1, 1992, Northern Natural Gas Company (Northern), on April 15, 1992, tendered for filing changes in its F.E.R.C. Gas Tariff, Third Revised Volume No. 1 (Volume No. 1 Tariff) and Original Volume No. 2 (Volume No. 2 Tariff).

The instant filing establishes a mechanism to direct bill or refund to

customers any over-or-underrecovery related to the service to those customers whose sales service is abandoned as a result of termination, reduction or conversion, regardless of whether or when the PGA is subsequently suspended or terminated.

Northern states that copies of the filing were served on Northern's jurisdictional sales customers and interested state commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before April 29, 1992. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 92-9840 Filed 4-27-92; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TA92-1-28-005]

Panhandle Eastern Pipe Line Co.; Compliance Filing

April 22, 1992.

Take notice that Panhandle Eastern Pipe Line Company (Panhandle) on March 30, 1992, tendered for filing the following revised tariff sheets to its FERC Gas Tariff, Original Volume No. 1.

2nd Sub 4th/Eighty-Eighth/Sheet No. 3-A
2nd Sub 4th/Second/Sheet No. 3-A.1
2nd Sub 4th/Sixty-Fifth/Sheet No. 3-B
2nd Sub 4th/Twelfth/Sheet No. 3-B.1

Panhandle states that on February 28, 1992 in the above-referenced proceeding, the Federal Regulatory Commission (Commission) issued an order accepting for filing and suspending tariff sheets filed by Panhandle subject to refund and conditions. Ordering Paragraph (E) of the Commission's Order directed Panhandle to file within 30 days of issuance of this order, revised rates and additional information to substantiate the Demand D-1 and D-2 billing determinants.

Panhandle further states that the revised tariff sheets filed herewith reflect an increase of $0.77 for Panhandle's D-1 demand rate from the revised annual PGA filing on February 4, 1992 in Docket No. TQ92-2-28-000.

Panhandle states that copies of its filing have been served on all jurisdictional sales customers and applicable state regulatory agencies.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before April 29, 1992. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 92-9841 Filed 4-27-92; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP92-118-001]

Panhandle Eastern Pipe Line Co.; Proposed Changes in FERC Gas Tariff

April 22, 1992.

Take notice that Panhandle Eastern Pipe Line Company (Panhandle) on April 15, 1992, tendered for filing the following tariff sheets to its FERC Gas Tariff, Original Volume No. 1:

First Revised Sheet No. 43-14.7
First Revised Sheet No. 43-14.8
Original Sheet No. 43-14.8a

The subject tariff sheets bear an issue date of April 15, 1992 and a proposed effective date of April 1, 1992.

Panhandle states that this filing is being made in compliance with Ordering Paragraphs (B) and (C) of the Commission's order dated March 31, 1992 to provide for a reconciliation mechanism for the referenced take-or-pay settlement cost recovering filing and to provide an explanation for how Panhandle proposes to treat discounts consistent with Order Nos. 528-A and 528-B.

Panhandle states that copies of its filing have been served upon Panhandle's jurisdictional customers and interested state commissions. Panhandle also states that copies of the filing is also being served on all parties in Docket No. RP91-229-000 and parties in this proceeding.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedures, 18 CFR 385.211. All such protests should be filed on or before April 29, 1992. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 92-9842 Filed 4-27-92; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP91-229-000]

Panhandle Eastern Pipe Line Co., Notice of Cancellation and Rescheduling of Informal Settlement Conference

April 21, 1992.

Take notice that the informal settlement conference scheduled in this proceeding to commence on Wednesday, May 6, 1992, at 10 a.m., and continuing through Thursday, May 7, 1992, has been canceled. Instead, an informal settlement conference will be held commencing Tuesday, May 19, 1992 at 1 p.m. and continuing through Wednesday, May 20, 1992. The conference will be held at the offices of the Federal Energy Regulatory Commission, 810 First Street, NE., Washington, DC, for the purpose of exploring the possible settlement of the above-referenced docket.

Any party, as defined in 18 CFR 385.102(c) or any participant, as defined in 18 CFR 385.102(b) is invited to attend. Persons wishing to become a party must move to intervene and receive intervenor status pursuant to the Commission's regulations, 18 CFR 385.214.

For additional information, contact Carmen Gastilo at (202) 208-2182 or Joanne Leveque at (202) 208-5705.

Lois D. Cashell,

Secretary.

[FR Doc. 92-9779 Filed 4-27-92; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TM92-4-18-000]

Texas Gas Transmission Corp.; Proposed Changes in FERC Gas Tariff

April 22, 1992.

Take notice that on April 16, 1992 Texas Gas Transmission Corporation (Texas Gas) tendered for filing the following revised tariff sheets to its FERC Gas Tariff:

Original Volume No. 1

Fifty-fourth Revised Sheet No. 10
Fifty-fourth Revised Sheet No. 10A

Thirty-fifth Revised Sheet No. 11
Twenty-fifth Revised Sheet No. 11A
Twenty-fifth Revised Sheet No. 11B

First Revised Volume No. 2-A

Second Revised Sheet No. 14

The tariff sheets are being submitted as part of Texas Gas's Third Annual Reconciliation of Take-Or-Pay Settlement Payments (TOP Settlement Payments) contained in original Docket Nos. RP89-119, RP89-208, and RP90-58. The tariff sheets also restate the Commodity TOP Surcharge to be collected over a period not to exceed twelve months as agreed to and approve din the settlement of Docket No. RP91-61-003.

Texas Gas requests an effective date of May 1, 1992, for the proposed tariff sheets.

Copies of the revised tariff sheets are being mailed to Texas Gas's sales customers and transportation customers affected by the filing and interested sate commissions. Texas Gas will maintain copies of this filing at its Ownesboro, Kentucky, offices for public inspection during regular business hours.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North capitol Street, NE., Washington, DC 20426, in accordance with §§ 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before April 29, 1992. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 92-9843 Filed 4-27-92; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP92-19-003]

Transwestern Pipeline Co.; Compliance Filing

April 22, 1992.

Take notice that Transwestern Pipeline Company ("Transwestern") on April 2, 1992 tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following tariff sheets:

Effective April 1, 1992

6th Revised Sheet No. 28
3rd Revised Sheet No. 51A
6th Revised Sheet No. 68A
2nd Revised Sheet No. 80B
9th Revised Sheet No. 81
3rd Revised Sheet No. 92C
3rd Revised Sheet No. 92D

Transwestern states that the tariff sheets referenced above with an effective date of April 1, 1992 are being filed to comply with the Commission's Order ("Order") issued March 18, 1992 in Docket No. RP92-19-000. The Order required Transwestern to refile revised tariff sheets within fifteen (15) days to reflect "modified flexible receipt and delivery point procedures to permit primary firm shippers to return to their primary receipt and delivery points at any time during the month and to reflect the agreed upon valuation of past imbalances." The tariff sheets, according to Transwestern, include the provisions filed on October 31, 1992 in Docket No. RP92-19-000 as otherwise modified by the Commission's Order for alternate receipt points, alternate delivery points, and the valuation of past imbalances.

Transwestern requests waiver of any Commission Regulation and its tariff provisions as may be required to allow the tariff sheets referenced above to become effective on April 1, 1992.

Transwestern states that copies of the filing were served on its jurisdictional customers, interested state commissions, and all parties to this proceeding.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before April 29, 1992. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D Cashell,

Secretary.

[FR Doc. 92-9844 Filed 4-27-92; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP91-152-017]

Williams Natural Gas Co.; Proposed Changes in FERC Gas Tariff

April 22, 1992.

Take notice that Williams Natural Gas Company (WNG) on April 16, 1992 tendered for filing the following tariff sheets to its FERC Gas Tariff, First Revised Volume No. 1:

Effective November 7, 1991

Fourth Substitute Fourth Revised Sheet Nos. 6 and 6A
Sixth Substitute Fourth Revised Sheet No. 9

Effective December 22, 1991

First Substitute Fifth Revised Sheet No. 6A

Effective January 1, 1992

First Substitute Fifth Revised Sheet No. 6
First Substitute Sixth Revised Sheet No. 6A
First Substitute Fifth Revised Sheet No. 9

Effective February 1, 1991

First Substitute Seventh Revised Sheet No. 6
First Substitute Eighth Revised Sheet No. 6A
First Substitute Seventh Revised Sheet No. 9

WNG states that these tariff sheets are being filed in compliance with Commission order approving and modifying a settlement which was issued March 18, 1992, in the above referenced dockets. Ordering Paragraph (B) directed WNG to file tariff sheets to calculate its take-or-pay volumetric surcharge based on a throughput of 360 MMDth, effective November 7, 1991. WNG is filing proposed tariff sheets to be effective on November 7, 1991, as well as every effective date thereafter, for changes in the TOP Volumetric Surcharge.

WNG states that a copy of its filing was served on all jurisdictional customers and interested state commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with § 385.211 of the Commission's Rules and Regulations. All such protests should be filed on or before April 29, 1992. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 92-9845 Filed 4-27-92; 8:45 am]

BILLING CODE 6717-01-M

Office of Conservation and Renewable Energy

[Case No. F-049]

Energy Conservation Program for Consumer Products; Granting of the Application for Interim Waiver and Publishing of the Petition for Waiver of DOE Furnace Test Procedures From Rheem Manufacturing Company

AGENCY: Office of Conservation and Renewable Energy, Department of Energy.

SUMMARY: Today's notice publishes a letter granting an Interim Waiver to Rheem Manufacturing Company (Rheem) from the existing Department of Energy (DOE) test procedure for furnaces regarding blower time delay for the company's GVG line of gas furnaces.

Today's notice also publishes a "Petition for Waiver" from Rheem. Rheem's Petition for Waiver requests DOE to grant relief from the DOE furnace test procedure relating to the blower time delay specification. Rheem seeks to test using a blower delay time of 30 seconds for its GVG line of gas furnaces instead of the specified 1.5-minute delay between burner on-time and blower on-time. DOE is soliciting comments, data, and information respecting the Petition for Waiver.

DATES: DOE will accept comments, data, and information not later than May 28, 1992.

ADDRESSES: Written comments and statements shall be sent to: Department of Energy, Office of Conservation and Renewable Energy, Case No. F-049, Mail Stop CE-90, Room 6B-025, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586-0561.

FOR FURTHER INFORMATION CONTACT:

Cyrus H. Nasseri, U.S. Department of Energy, Office of Conservation and Renewable Energy, Mail Station CE-43, Forrestal Building, 1000 Independence Avenue, SW. Washington, DC 20585, (202) 586-9127.

Eugene Margolis, Esq., U.S. Department of Energy, Office of General Counsel, Mail Station GC-41, Forrestal Building, 1000 Independence Avenue, SW. Washington, DC 20585, (202) 586-9507.

SUPPLEMENTARY INFORMATION: The Energy Conservation Program for Consumer Products (other than automobiles) was established pursuant to the Energy Policy and Conservation Act (EPCA), Public Law 94-163, 89 Stat. 917, as amended by the National Energy Conservation Policy Act (NECPA), Public law 95-619, 92 Stat. 3266, the National Appliance Energy Conservation Act of 1987 (NAECA), Public Law 100-12, and the National Appliance Energy Conservation Amendments of 1988 (NAECA 1988), Public law 100-357, which requires DOE to prescribe standardized test procedures to measure the energy consumption of certain consumer products, including furnaces. The intent of the test procedures is to provide a comparable measure of energy consumption that will assist consumers in making purchasing decisions. These test procedures appear at 10 CFR part 430, subpart B.

DOE amended the prescribed test procedures by adding 10 CFR 430.27 on September 26, 1980, creating the waiver process. 45 FR 64108. Thereafter DOE further amended the appliance test procedure waiver process to allow the Assistant Secretary for Conservation and Renewable Energy (Assistant Secretary) to grant an Interim Waiver from test procedure requirements to manufacturers that have petitioned DOE for a waiver of such prescribed test procedures. 51 FR 42823, November 26, 1986.

The waiver process allows the Assistant Secretary to waive temporarily test procedures for a particular basic model when a petitioner shows that the basic model contains one or more design characteristics which prevent testing according to the prescribed test procedures or when the prescribed test procedures may evaluate the basic model in a manner so unrepresentative of its true energy consumption as to provide materially inaccurate comparative data. Waivers generally remain in effect until final test procedure amendments become effective, resolving the problem that is the subject of the waiver.

The Interim Waiver provisions added by the 1986 amendment allow the Assistant Secretary to grant an Interim Waiver when it is determined that the applicant will experience economic hardship if the Application for Interim Waiver is denied, if it appears likely that the Petition for Waiver will be granted, and/or the Assistant Secretary determines that it would be desirable for public policy reasons to grant immediate relief pending a determination on the Petition for Waiver. An Interim Waiver remains in effect for a period of 180 days or until DOE issues its determination on the Petition for Waiver, whichever is sooner, and may be extended for an additional 180 days, if necessary.

On February 12, 1992, Rheem filed an Application for Interim Waiver regarding blower time delay. Rheem's Application seeks an Interim Waiver from the DOE test provisions that require a 1.5-minute time delay between the ignition of the burner and starting of the circulating air blower. Instead, Rheem requests the allowance to test using a 30-second blower time delay when testing its GVG line of gas furnaces. Rheem states that the 30-second delay is indicative of how these furnaces actually operate. Such a delay results in an energy savings of approximately 2.0 percent. Since current DOE test procedures do not address this variable blower time delay, Rheem asks that the Interim Waiver be granted.

Previous waivers for this type of timed blower delay control have been granted by DOE to Coleman Company, 50 FR 2710, January 18, 1985; Magic Chef Company, 50 FR 41553, October 11, 1985; Rheem Manufacturing Company, 53 FR 48574, December 1, 1988, 55 FR 3253, January 31, 1990, and 56 FR 2920, January 25, 1991; Trane Company, 54 FR 19226, May 4, 1989, and 56 FR 6021, February 14, 1991; Lennox Industries, 55 FR 50224, December 5, 1990; DMO Industries, 56 FR 4622, February 5, 1991; Heil-Quaker Corporation, 56 FR 6019, February 14, 1991; Carrier Corporation, 56 FR 6018, February 14, 1991; Inter-City Products Corporation, 55 FR 51487, December 14, 1991, and 56 FR 63945, December 6, 1991; Amana Refrigeration Inc., 56 FR 27958, June 18, 1991, and 56 63940, December 6, 1991; Snyder General Corporation, 56 FR 45960, September 9, 1991; Goodman Manufacturing Corporation, 56 FR 51713, October 15, 1991; Armstrong Air Conditioning, Inc., 57 FR 899, January 9, 1992; Thermo Products, Inc., 57 FR 903, January 9, 1992; and the Ducane Company, 56 FR 63943, December 6, 1991. Thus, it appears likely that the Petition for Waiver will be granted for blower time delay.

In those instances where the likely success of the Petition for Waiver has been demonstrated based upon DOE having granted a waiver for a similar product design, it is in the public interest to have similar products tested and rated for energy consumption on a comparable basis.

Therefore, based on the above, DOE is granting Rheem an Interim Waiver for its GVG line of gas furnaces. Pursuant to paragraph (e) of section 430.27 of the Code of Federal Regulations Part 430, the following letter granting the Application for Interim Waiver to Rheem was issued.

Pursuant to paragraph (b) of 10 CFR part 430.27, DOE is hereby publishing the "Petition for Waiver" in its entirety. The petition contains no confidential information. DOE solicits comments, data, and information respecting the petition.

Issued in Washington, DC, April 17, 1992.

J. Michael Davis,

Assistant Secretary Conservation and Renewable Energy.

Mr. Daniel J. Canclini,

Vice-President, Product Development and Research Engineering, Rheem Manufacturing Company, P.O. Box 17010, Fort Smith, AR 72917-7010.

Dear Mr. Canclini: This is in response to your February 12, 1992, Application for Interim Waiver and Petition for Waiver from the Department of Energy (DOE) test procedure for furnaces regarding blower time delay for Rheem Manufacturing Company (Rheem) GVG line of gas furnaces.

Previous waivers for this type of timed blower delay control have been granted by DOE to Coleman Company, 50 FR 2710, January 18, 1985; Magic Chef Company, 50 FR 41553, October 11, 1985; Rheem Manufacturing Company, 53 FR 48574, December 1, 1988, 55 FR 3253, January 31, 1990, and 56 FR 2920, January 25, 1991; Trane Company, 54 FR 19226, May 4, 1989, and 56 FR 6021, February 14, 1991; Lennox Industries, 55 FR 50224, December 5, 1990; DMO Industries, 56 FR 4622, February 5, 1991; Heil-Quaker Corporation, 56 FR 6019, February 14, 1991; Carrier Corporation, 56 FR 6018, February 14, 1991; Inter-City Products Corporation, 55 FR 51487, December 14, 1991, and 56 FR 63945, December 6, 1991; Amana Refrigeration Inc., 56 FR 27958, June 18, 1991, and 56 63940, December 6, 1991; Snyder General Corporation, 56 FR 45960, September 9, 1991; Goodman Manufacturing Corporation, 56 FR 51713, October 15, 1991; Armstrong Air Conditioning, Inc., 57 FR 899, January 9, 1992; Thermo Products, Inc., 57 FR 903, January 9, 1992; and The Ducane Company, 56 FR 63943, December 6, 1991.

Rheem's Application for Interim Waiver does not provide sufficient information to evaluate what, if any, economic impact or competitive disadvantage Rheem will likely experience absent a favorable determination on its application. However, in those instances where the likely success of the Petition for Waiver has been demonstrated, based upon DOE having granted a waiver for a similar product design, it is in the public interest to have similar products tested and rated for energy consumption on a comparable basis.

Therefore, Rheem's Application for an Interim Waiver from the DOE test procedure for its GVG line of gas furnaces regarding blower time delay is granted.

Rheem shall be permitted to test its GVG line of gas furnaces on the basis of the test procedures specified in 10 CFR Part 430, Subpart B, Appendix N, with the modification set forth below.

(i) Section 3.0 in Appendix N is deleted and replaced with the following paragraph:

3.0 Test Procedure. Testing and measurements shall be as specified in section 9 in ANSI/ASHRAE 103-82 with the exception of sections 9.2.2, 9.3.1, and 9.3.2, and the inclusion of the following additional procedures:

(ii) Add a new paragraph 3.10 in Appendix N as follows:

3.10 Gas- and Oil-Fueled Central Furnaces. After equilibrium conditions are achieved following the cool-down test and the required measurements performed, turn on the furnace and measure the flue gas temperature, using the thermocouple grid described above, at 0.5 and 2.5 minutes after the main burner(s) comes on. After the burner start-up, delay the blower start-up by 1.5 minutes (t−), unless: (1) the furnace employs a single motor to drive the power burner and the indoor air circulation blower, in which case the burner and blower shall be started together; or (2) the furnace is designed to operate using an unvarying delay time that is other than 1.5 minutes, in which case the fan control shall be permitted to start the blower; or (3) the delay time results in the activation of a temperature safety device which shuts off the burner, in which case the fan control shall be permitted to start the blower. In the latter case, if the fan control is adjustable, set it to start the blower at the highest temperature. If the fan control is permitted to start the blower, measure time delay, (t−), using a stop watch. Record the measured temperatures. During the heat-up test for oil-fueled furnaces, maintain the draft in the flue pipe within +0.01 inch of water column of the manufacturer's recommended on-period draft.

This Interim Wavier is based upon the presumed validity of statements and all allegations submitted by the company. This Interim Waiver may be revoked or modified at any time upon a determination that the factual basis underlying the application is incorrect.

The Interim Waiver shall remain in effect for a period of 180 days or until DOE acts on the Petition for Waiver, whichever is sooner, and may be extended for an additional 180-day period, if necessary.

Sincerely,

J. Michael Davis, P.E.

Assistant Secretary, Conservation and Renewable Energy.

Rheem Manufacturing Company

Air Conditioning Division

February 12, 1992

Mr. Cyrus Nasser,

Assistant Secretary, Conservation and Renewable Energy, United States Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585

Dear Mr. Nasser: This is a petition for waiver and application for interim waiver submitted pursuant to Title 10 CFR Part 430.27. Waiver is requested from the furnace test procedure as prescribed in Appendix N to Subpart B of Part 430. The test procedure requires a 1.5 minute delay between burner and blower start-up. Rheem is requesting authorization to use a 30 second delay instead of 1.5 minutes for our Series (-)GVG horizontal residential gas-fired furnaces

Rheem will be manufacturing these furnaces with an electronic device that controls the blower operation on a timing sequence as opposed to temperature.

Improved energy efficiency is achieved by reducing on cycle losses. Under the Appendix N procedures, the stack temperature is allowed to climb at a faster rate than it would with a 30 second blower on time, allowing energy to be lost out the vent system. This waste of energy would not occur in actual operation. If this petition is granted, the true blower on time delay would be used in the calculations.

The current test procedures do not give Rheem credit for the energy savings which averages approximately 2%. This improvement is an average reduction of 20% of the normal on cycle energy losses. Rheem is of the opinion that a 20% reduction is a worthwhile energy savings.

Rheem has been granted a waiver permitting the 30 second blower on time to be used in the efficiency calculations for our (-)GEB and (-)GKA series condensing furnaces and/or (-)GDE and (-)GLE series furnaces. Several other manufacturers of gas furnaces have also been granted a waiver to permit calculations based on timed blower operation. Also, proposed ASHRAE Standard 103-1982R of 9/25/87 paragraph 9.5.1.2.2 specifically addresses the use of timed blower operation.

Confidential comparative test data is available to you upon your request, confirming the above energy savings.

Manufacturers that domestically market similar products are being sent a copy of this petition for waiver and petition for interim waiver.

Sincerely,

Daniel J. Canclini,

Vice-President, Product Development and Research Engineering.

[FR Doc. 92-9887 Filed 4-27-92; 8:45 am]

BILLING CODE 6450-01-M

Western Area Power Administration

Central Valley Project—Call for Power Allocation Applications for the 1994 Power Marketing Plan

AGENCY: Western Area Power Administration, DOE.

ACTION: Call for power applications for the 1994 Power Marketing Plan.

SUMMARY: The Western Area Power Administration (Western), a Federal power marketing agency of the Department of Energy (DOE), is developing a 1994 Power Marketing Plan (Plan) for the Central Valley Project (CVP), California. If Western decides to market power in accordance with the proposed Plan, Western will market 529.9 megawatts (MW) which represents about 35 percent of the CVP's marketable power. This power will be available upon expiration of 63 Western power contracts on or about June 30 1994. The proposed Plan, published

August 22, 1991, in the **Federal Register** (56 FR 41683), provides for marketing 529.9 MW, of which up to 29.2 MW may be available to new customers, through December 31, 2004.

To establish an orderly administrative process, this notice requests that entities submit a formal application for allocations of CVP power. If the final Plan provides for allocations, all applications will be considered by Western's Administrator to determine allocations under the Plan.

Western has decided to do additional environmental analysis to amend the existing environmental assessment (EA) (DOE/EA-0467). As a result of the existing EA, DOE issued a Finding of No Significant Impact (FONSI) on April 24, 1991, for the proposed Plan. The proposed Plan and FONSI are subject to verification of the environmental analysis.

On or about September 1992, Western plans to publish a **Federal Register** notice which will discuss the additional information for the EA, announced the final Plan, and discuss the issues raised in comments to the proposed Plan received by Western. If the final Plan provides for the allocation of CVP power, the September notice also will include the proposed allocations of power. Final allocations are tentatively planned to be published in the **Federal Register** in October 1992.

Background

Western initiated the development of the Plan for the CVP with a January 31, 1989, public information meeting. In a brochure distributed at that meeting, Western explained the need for a power marketing plan to market CVP power that would become available with the expiration of 63 Western power contracts on or about June 30, 1994. Western then published a **Federal Register** notice on August 11, 1989 (54 FR 33064), which outlined four alternatives that Western believed would define options to market the CVP resource. The August notice informed the public that Western would conduct an environmental analysis on all the alternatives in accordance with the National Environmental Policy Act (NEPA), and announced the dates of public scoping meetings where Western would accept comments on the scope of the environmental analysis. In conjunction with these scoping meetings, Western announced that it would hold a public information meeting and a public comment forum to accept comments on the alternatives in the draft Plan. A November 20, 1989, deadline was set for receipt of written comments on scoping of the environmental analysis of the alternatives in the draft Plan.

The public information meeting was held on September 12, 1989, with the public comment forum following on October 20, 1989. Western prepared an EA with four alternatives, each of which had several options. Western used all available information gathered in the public process and developed the proposed Plan which was published in the **Federal Register** on August 22, 1991 (56 FR 41683).

If Western does not change the proposed Plan as specified in the August 22, 1991, **Federal Register** (56 FR 41683) as a result of the additional environmental analysis, then Western will market 529.9 MW through December 31, 2004, divided into four classes of power. The proposed Plan provides for allocating 371 MW of Long-Term Firm Power to existing customers and 8.2 MW of Long-Term Firm Power to new customers. Long-Term Firm Power means firm power allocated by Western and subject to the terms and conditions specified in the Western electric service contract. The proposed Plan also provides for allocating 40.7 MW of Type III Withdrawable Power to customers presently receiving this class of electric service. Type III Withdrawable Power means firm power which is withdrawable to protect the 1,152-MW load level before withdrawal of other classes of noninterruptible power. The proposed Plan provides for allocating 9 MW of Diversity Power to customers presently receiving Diversity Power and allocating 21 MW of Diversity Power to new and existing customers. Diversity Power means firm power made available because of the diversity of Western customers' peak demands at the time of Western's peak demand. A Diversity Power customer must shed a specified amount of load at Western's request at the time of Western's simultaneous peak demands. In addition, the proposed Plan provides for allocating 80 MW of Curtailable Power to the city of Santa Clara which presently has a contract for this power Curtailable Power means power that may be curtailed on a real-time scheduling basis, by Western and at Western's sole discretion, to protect the 1,152-MW load level. Long-Term Firm Power, Type III Withdrawable Power, Diversity Power, and Curtailable Power are subject to additional terms and conditions specified in Western's electric service contracts.

Western held a public information forum on the proposed Plan on August 27, 1991. A public comment forum followed on September 16, 1991, to accept oral and written comments on the proposed Plan. The formal comment and consultation period ended October 16, 1991. Approximately 100 comments were received from nearly 40 sources. Some comments requested increased power allocations, an increase in the amount of Diversity Power available, and clarification of the general allocation criteria. One comment suggested that Western withdraw its proposed Plan in order to prepare an environmental impact statement (EIS) on the proposed alternatives.

Western received a letter from members of Congress requesting an explanation of the basis for Western's decision not to prepare an EIS on the proposed Plan. Responses to the letter and a followup inquiry were prepared by Western and are available upon request. Western responded that an EA was the appropriate level of NEPA consideration for the Plan due to the limited scope of the Plan, the presence of reregulation dams immediately downstream of each major generation facility, and the United States Bureau of Reclamation's (Reclamation) control of the water operations of the CVP. Reclamation's water operations take precedence over Western's ability to affect the river ecosystems downstream of CVP dams as a result of power generation. Western has determined, however, that additional analysis is needed relating to the EA. The additional analysis will include, but will not be limited to, a description of the existing environment, an analysis of the impacts to the reregulation reservoirs, and a description of the operation of the CVP system. Upon completion of the additional analysis, the EA will be reviewed and, if appropriate, additional environmental documentation will be issued.

DATES: Applications for an allocation of power must be received by certified mail in Western's Sacramento Area Office at the address below from each applicant no later than 5 p.m., local time, May 28, 1992. Upon completion of the additional environmental analysis, a tentative date of September 1992 has been set to announce the final Plan and, if appropriate, the proposed allocations. If the final Plan provides for allocations of CVP power, final allocations will subsequently be published in the **Federal Register** on or about October 1992.

FOR FURTHER INFORMATION CONTACT: Inquiries on the Plan and the applications for power allocations should be directed to: Mr. David G. Coleman, Area Manager, Sacramento Area Office, Western Area Power

Administration, 1825 Bell Street, suite 105, Sacramento, CA 95825–1097, Telephone: (916) 649–4418.

All documentation made or retained by Western for the purpose of developing the Plan is and will be available for inspection and copying at the above-mentioned address.

SUPPLEMENTARY INFORMATION:

A. Procedures

1. Applications for Power

This notice formally requests applications for CVP power. Applicant Profile Data (APD) is requested from all entities wishing to receive an allocation so that Western will have a uniform basis upon which to evaluate the applications. To be considered, applicants must advise the Area Manager of their request to receive an allocation of power by submitting the APD on or before 30 days after the date this **Federal Register** notice is published to the address above. To ensure that full consideration is given to all applicants, Western will not consider applications or requests for power submitted prior to the publication of this notice.

2. Applicant Profile Data

The content and format of the APD is outlined below. The information should be submitted in the sequence listed below. Please provide all information requested or the most reasonable estimates that are available. Please indicate if the requested information is not applicable or not available. Western will request in writing additional information from any applicant whose application is determined to be deficient. The applicant shall have 10 working days from the postmark date on Western's request to provide the information. Western requires that the APD be typed and that six copies be submitted to the above-mentioned address by certified mail. The burden of ensuring consistency of the content of all six copies rests with the applicant. Western is not responsible for errors in data or missing pages.

All items of information in the APD should be answered as if prepared by the organization seeking the allocation of Federal power. The APD shall consist of the following:

a. Applicant

(1) Applicant's name and address.

(2) Person(s) representing applicant: Please provide the name, address, title, and telephone number of such person(s).

(3) Type of organization: For example, municipality, rural electric cooperative, irrigation district, State agency, or Federal agency.

(4) Parent organization.

(5) Names of members.

(6) Applicable law under which organization was established.

(7) Organization's geographic service area: If readily available, submit a map of the service area, and indicate the date prepared.

(8) Documentation of applicant's ability to receive and use or receive and distribute Federal power as of January 1, 1992.

b. Service Requested

The class(es) or type(s) and amount(s) of electrical service requested.

c. Loads

(1) Maximum demand (kilowatts (kW)) and energy use (kilowatthours (kWh)), for each month for each of the calendar years 1989 and 1990 (new customers only).

(2) Average annual and monthly load factors for 1989 and 1990 (new customers only).

(3) Factors or conditions which may significantly change peak demands or load duration or profile curves for the next 3 years.

d. Transmission

(1) Points of delivery: Please provide the preferred point(s) of delivery on Western's system or a third party's system, the voltage of service required, and the capacity desired at each point of delivery.

(2) Transmission arrangements: Describe the transmission arrangements necessary to delivery power for the requested point(s) of delivery.

e. Demand-Side Management Programs

Please provide a description of current and planned demand-side management (DSM) programs. DSM programs include, but are not limited to, lighting improvements (new and retrofit), building energy efficiency projects, thermal energy storage, air conditioning load shedding, and commercial/industrial load curtailment.

f. Assistance in Meeting Customer Loads

Please provide a description of current and future capabilities to assist Western in meeting its load requirements. Such capabilities could include, but are not limited to, the willingness to provide transmission service, transmission access, joint project participation, or any other capabilities that may assist Western in meeting its load requirements.

g. New Irrigation Districts

Please provide documentation if the irrigation district transmits CVP power or receives or purchases CVP water (new irrigation districts only).

h. Other Information

The applicant is welcome to provide any other information pertinent to receiving an allocation.

i. Signature

The signature and title of an appropriate official who is able to attest to the validity of the information submitted and who is authorized to submit the application is required.

3. Allocation Process

After completion of the additional environmental analysis, Western may finalize the Plan and determine whether or not to allocate power under the Plan. If Western decides to allocate power, it will determine which applications meet the requirements of the Plan, and then exercise its discretion provided by law in allocating the power to eligible applicants. If Western decides to allocate power under the final Plan, an announcement of the final Plan and proposed allocations will be published in the **Federal Register** on or about September 1992.

4. Eligibility Criteria

If the proposed Plan is not modified, Western will apply the following eligibility criteria, published in the August 22, 1991, proposed Plan, to all applicants seeking an allocation of power.

a. Only preference entities as defined by section 9(c) of the Reclamation Project Act of 1939, 43 U.S.C. 485h(c), as amended and supplemented, will be eligible to receive an allocation.

b. A preference entity must exist, operate, and be ready, willing, and able to receive and use, or receive and distribute, Federal power as of January 1, 1992.

c. A preference entity not presently receiving Long-Term Firm Power under a contract expiring in 1994 must be located within the Pacific Gas and Electric Company (PG&E) service area. Western will provide maps of the PG&E service area to any interested party upon request.

5. Allocation Criteria

If the proposed Plan is not modified, Western will apply the following allocation criteria, published in the August. 22, 1991, proposed Plan, to all applicants seeking an allocation of power.

a. Allocations of power will be made in amounts as determined solely by Western in the exercise of its discretion under Reclamation law.

b. The minimum allocation shall be 500 kW. Western may waive this requirement for preference entities which historically have had loads under 500 kW and are directly connected to Western's transmission system.

c. Among new irrigation or water district applicants, greater consideration will be given to irrigation or water districts which transmit CVP power or receive or purchase CVP water.

d. Among all applicants, greater consideration will be given in allocating power to those applicants who can demonstrate a diversity contribution at the time of Western's simultaneous peak.

e. Among all applicants, greater consideration will be given to those applicants who have instituted and continue to actively pursue demand-side management activities.

f. Among all applicants, greater consideration will be given to those applicants who assist Western in its mission of delivering Federal power at the lowest possible cost consistent with sound business principles by providing such factors as, among others, transmission access to low-cost sources of power and assistance in providing efficient and reliable electrical service.

6. Contract Process

If power is allocated under the final Plan, Western will begin the contracting process with the allottees after publishing the final allocations in the **Federal Register** tentatively scheduled for October 1992. A prototype contract for electric service has been prepared and copies are available from the Sacramento Area Office upon request. The prototype contract shall be used by all customers to contract for power allocated under the Plan. Allottees shall have 6 months from the date offered by Western to execute contracts for allocations under the Plan. Contracts will be effective on the later of the effective date of service under a new electric service contract or July 1, 1994.

B. Regulatory Procedure Requirements

1. Regulatory Flexibility Analysis

Pursuant to the Regulatory Flexibility Act of 1980, 5 U.S.C. 601, *et seq.*, each agency,when required to publish a final rule, is further required to prepare and make available for public comment an initial regulatory flexibility analysis to describe the impact of the rule on small entities. Western has determined that (1) this rule making relates to service offered by Western and, therefore, is not a rule within the purview of the Act and (2) the impacts of an allocation from Western would not cause an adverse economic impact to such entities. The requirements of this Act can be waived if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. By his execution of this **Federal Register** notice, Western's Administrator certifies that no significant economic impact on a substantial number of small entities will occur.

2. Environmental Compliance

Please see Background section above.

3. Paperwork Reduction Act of 1980

The Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, requires that certain information collection requirements be approved by the Office of Management and Budget (OMB) before information is requested of the public. OMB has issued a final rule on the Paperwork Burdens on the Public (48 FR 13666) dated March 31, 1983.

4. Determination Under Executive Order 12291

The DOE has determined that the call for applications is not a major rule because it does not meet the criteria of section 1(b) of Executive Order 12291, 46 FR 13193 (February 19, 1981). Western has an exemption from sections 3, 4, and 7 of Executive Order 12291; accordingly, no clearance of this Plan by the OMB is required.

Issued at Golden, Colorado, April 10, 1992.

William H. Clagett,

Administrator.

[FR Doc. 92-9886 Filed 4-27-92; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[OPPTS-44584; FRL-4059-7]

TSCA Chemical Testing; Receipt of Test Data

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the receipt of test data on methylethylketoxime (MEKO) (CAS No. 96-29-7), submitted pursuant to a final test rule under the Toxic Substances Control Act (TSCA). EPA is also correcting the notice announcing the receipt of test data published on March 10, 1992 (57 FR 8454), describing the oncogenic potential of 2-ethylhexanol in rats. Publication of this notice is in compliance with section 4(d) of TSCA.

FOR FURTHER INFORMATION CONTACT: David Kling, Acting Director, Environmental Assistance Division (TS-799), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-543B, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: Section 4(d) of TSCA requires EPA to publish a notice in the **Federal Register** reporting the receipt of test data submitted pursuant to test rules promulgated under section 4(a) within 15 days after it is received.

I. Test Data Submissions

Test data for MEKO were submitted by the Industrial Health Foundation, Inc., pursuant to a test rule at 40 CFR 799.2700. The data were received by EPA on March 31, 1992. The submission describes a two-generation reproduction study of MEKO administered to CD Sprague-Dawley rats. Health effects testing is required by this test rule. This chemical is sold primarily as a nonreactive antiskinning agent in alkyd surface coatings and paints. It is also used as a blocking agent for isocyanates and siloxanes.

EPA is also correcting the notice announcing the receipt of test data for 2-ethylhexanol; published at 57 FR 8454, March 10, 1992. Accordingly, in FR Doc. 92-5592, unit I, page 8455, "18 months," is corrected to read "24 months."

EPA has initiated its review and evaluation process for these data submissions. At this time, the Agency is unable to provide any determination as to the completeness of the submissions.

II. Public Record

EPA has established a public record for this TSCA section 4(d) receipt of data notice (docket number OPPTS-44584). This record includes copies of all studies reported in this notice. The record is available for inspection from 8 a.m. to 12 noon, and 1 p.m. to 4 p.m., Monday through Friday, except legal holidays, in the TSCA Public Docket Office, Rm. NE-G004, 401 M St., SW., Washington, Dc 20460.

Authority: 15 U.S.C. 2603.

Dated: April 16, 1992.

Charles M. Auer,

Director, Existing Chemical Assessment Division, Office of Pollution Prevention and Toxics.

[FR Doc. 92-9743 Filed 4-27-92; 8:45 am]

BILLING CODE 6560-50-F

[OPPTS-59307; FRL 4062-8]

Certain Chemical; Test Market Exemption Application

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA may upon application exempt any person from the premanufacturing notification requirements of section 5(a) or (b) of the Toxic Substance Control Act (TSCA) to permit the person to manufacture or process a chemical for test marketing purposes under section 5(h)(1) of TSCA. Requirements for test marketing exemption (TME) applications, which must either be approved or denied within 45 days of receipt are discussed in EPA's final rule published in the **Federal Register** of May 13, 1983 (48 FR 21722). This notice, issued under section 5(h)(6) of TSCA, announces receipt of 2 application for exemption, provides a summary, and requests comments on the appropriateness of granting these exemptions.

DATES:

Written comments by:
T 92-8, May 10, 1992.
T 92-9, May 15, 1992.

ADDRESSES: Written comments, identified by the document control number "(OPPTS-59307)" and the specific TME number should be sent to: Document Processing Center (TS-790), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW, Rm. 201ET, Washington, DC 20460, (202) 260-1532.

FOR FURTHER INFORMATION CONTACT: David Kling, Acting Director, Environmental Assistance Division (TS-799), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. EB-545, 401 M St., SW, Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: The following notice contains information extracted from the nonconfidential version of the submission provided by the manufacturer of the TME received by EPA. The complete nonconfidential document is available in the TSCA Public Docket Office NE-G004 at the above address between 8 a.m. and noon and 1 p.m. and 4 p.m., Monday through Friday, excluding legal holidays.

T 92-8

Close of Review Period. May 24, 1992.
Importer. Confidential.
Chemical. (G) Quarernary ammonium sulfobetaine.
Use/Import. (G) Detergent and bleach ingredient. Import range: Confidential.

T 92-9

Close of Review Period. May 29, 1992.
Importer. Confidential.
Chemical. (G) Alkylamine.
Use/Import. (G) Flotation agent. Import range: Confidential.

Dated: April 21, 1992.

Steven Newburg-Rinn,
Acting Director, Information Management Division, Office of Pollution Prevention and Toxics.

[FR Doc. 92-9745 Filed 4-27-92 8:45 am]
BILLING CODE 6560-50-F

[OPPTS-59305 ; FRL-4060-7]

Certain Chemicals; Approval of Test Marketing Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's approval of applications for test marketing exemptions (TMEs) under section 5(h)(1) of the Toxic Substances Control Act (TSCA) and 40 CFR 720.38. EPA has designated these applications as TME-92-4, TME-92-5, and TME-92-6. The test marketing conditions are described below.

EFFECTIVE DATES: April 20, 1992. Written comments will be received until May 13, 1992.

ADDRESSES: Written comments, identified by the document control number "[OPPTS-59305]" and the specific TME numbers "[TME-92-4, TME-92-5, and TME-92-6]" should be sent to: Document Control Officer (TS-790), Confidential Data Branch, Information Management Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-201, 401 M St., SW., Washington, DC 20460, (202) 260-1532.

FOR FURTHER INFORMATION CONTACT: Mark Howard, New Chemicals Branch, Chemical Control Division (TS-794), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-611, 401 M St. SW., Washington, DC 20460,(202) 260-4143.

SUPPLEMENTARY INFORMATION: Section 5(h)(1) of TSCA authorizes EPA to exempt persons from premanufacture notification (PMN) requirements and permit them to manufacture or import new chemical substances for test marketing purposes if the Agency finds that the manufacture, processing, distribution in commerce, use, and disposal of the substances for test marketing purposes will not present an unreasonable risk of injury to human health or the environment. EPA may impose restrictions on test marketing activities and may modify or revoke a test marketing exemption upon receipt of new information which casts significant doubt on its finding that the test marketing activity will not present an unreasonable risk of injury.

EPA hereby approves TME-92-4, TME-92-5, and TME-92-6. EPA has determined that test marketing of the new chemical substances described below, under the conditions set out in the TME applications, and for the time periods and restrictions specified below, will not present an unreasonable risk of injury to human health or the environment. Production volume, use, and the number of customers must not exceed that specified in the applications. All other conditions and restrictions described in the applications and in this notice must be met.

Inadvertently, notice of receipt of the applications was not published. Therefore, an opportunity to submit comments is being offered at this time. The complete nonconfidential document is available in the Public Reading Room NE G004 at the above address between 8 a.m. and 4 p.m., Monday through Friday, excluding legal holidays. EPA may modify or revoke the test marketing exemptions if comments are received which cast significant doubt on its finding that the test marketing activities will not present an unreasonable risk of injury.

The following additional restrictions apply to TME-92-4, TME-92-5, and TME-92-6. A bill of lading accompanying each shipment must state that the use of the substance is restricted to that approved in the TME. The test market substances may only be applied to cloth through the silk screen process. In addition, the Company shall maintain the following records until 5 years after the date they are created, and shall make them available for inspection or copying in accordance with section 11 of TSCA:

1. The applicant must maintain records of the quantity of each TME substance imported and the date of import.

2. The applicant must maintain records of dates of the shipments to each customer and the quantities supplied in each shipment.

3. The applicant must maintain copies of the bill of lading that accompanies each shipment of the TME substances.

T-92-4

Date of Receipt: February 24, 1992.

Close of Review Period: April 22, 1992. The extended comment period will close May 13, 1992.

Applicant: Matsui International Co., Inc.

Chemical: Spiro[2*H*-indole-2,3'-[3*H*]naphth[2,1-*b*][1,4]oxizane],6'-(2,3-dihydro-1*H*-indol-1-yl)-1,3-dihydro-1,3,3 trimethyl-;

Use: Photochromatic silk screen printing ink.

Production Volume: 30 kgs.

Number of Customers: 1.

Worker Exposure: During processing/use approximately 12 workers may be exposed dermally to 1950 milligrams per day up to 90 days if gloves are not worn.

Test Marketing Period: 90 days, commencing on first day of import.

T-92-5

Date of Receipt: February 24, 1992.

Close of Review Period: April 22, 1992. The extended comment period will close May 13, 1992.

Applicant: Matsui International Co., Inc.

Chemical: Spiro[2*H*-indole-2,3'-[3*H*]naphth[2,1- *b*][1,4]oxizane],1,3-dihydro-1,3,3-trimethyl-6'-(1-piperidinyl)-;

Use: Photochromatic silk screen printing ink.

Production Volume: 30 kgs.

Number of Customers: 1.

Worker Exposure: During processing/use approximately 12 workers may be exposed dermally to 1950 milligrams per day up to 90 days if gloves are not worn.

Test Marketing Period: 90 days, commencing on first day of import.

T-92-6

Date of Receipt: February 24, 1992.

Close of Review Period: April 22, 1992. The extended comment period will close May 13, 1992.

Applicant: Matsui International Co., Inc.

Chemicals: 3*H*-Naphtho[2,1-*b*]pyran, 3,3,-diphenyl-

Use: Photochromatic silk screen printing ink.

Production Volume: 50 kgs.

Number of Customers: 1.

Worker Exposure: During processing/use approximately 12 workers may be exposed dermally to 1950 milligrams per day up to 90 days if gloves are not worn.

Test Marketing Period: 90 days, commencing on first day of import.

Risk Assessment: EPA identified possible releases of up to 0.002 kilograms per day per substance to water but did not identify any significant human health effects or environmental risks for use during the test markets. Therefore, the test market activities will not present an unreasonable risk of injury to health or the environment.

The Agency reserves the right to rescind approval or modify the conditions and restrictions of an exemption should any new information come to its attention which casts significant doubt on its finding that the test marketing activities will not present an unreasonable risk of injury to health or the environment.

Dated: April 20, 1992.

John W. Melone,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

[FR Doc. 92-9739 Filed 4-27-92; 8:45 am]

BILLING CODE 6560-50-F

[FRL-4127-4]

National Pollutant Discharge Elimination System General Permit for Discharge of Storm Water Associated With Industrial Activity in the State of Oklahoma

AGENCY: Environmental Protection Agency (EPA).

ACTION: Supplemental notice of draft NPDES general permit for discharge of storm water associated with industrial activity in the State of Oklahoma.

SUMMARY: In the August 16, 1991, **Federal Register** (56 FR 40948), the Environmental Protection Agency published and requested comments on draft National Pollutant Discharge Elimination System (NPDES) general permits for point source discharge of storm water associated with industrial activity in States and Territories without authorized State NPDES programs (including Oklahoma) and on Indian lands and/or from Federal facilities in various other States. An important condition, limiting discharges in several areas of the State, was inadvertently omitted from the draft general permit for the State of Oklahoma. State law prohibits new point source discharges, or increased loads from existing point source discharges, to designated outstanding resource waters, sensitive public and private water supplies, and high quality waters of the State. In compliance with sections 402(a) and 301(b)(1)(C) of the Clean Water Act, EPA is amending the draft general permit for Oklahoma, proposing to prohibit new discharges of pollutants in storm water and increased pollutant loadings in existing storm water discharges to waterbodies listed under Oklahoma Water Quality Standards Rule 300.15.

DATES: Comments on this addition to the Oklahoma draft NPDES general permit, including any requests for a public hearing, must be received on or before May 28, 1992.

ADDRESSES: The public should send an original and two copies of their comments addressing this addition to the Oklahoma general permit to Brent Larsen, NPDES Permits Branch (6W-PM), Environmental Protection Agency, Region 6, 1445 Ross Avenue, suite 1200, Dallas, Texas 75202-2733. All comments or requests for a public hearing must be limited to factors or issues directly related to today's addition to the draft general permit for Oklahoma. Comments on today's notice will be added to the Administrative Record located at EPA Headquarters, EPA Public Information Reference Unit, Room 2402, 401 M Street SW., Washington, DC 20460. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: For further information on this addition to the draft general permit for Oklahoma contact the EPA Region 6 Storm Water Hotline at (214) 655-7185 or: Brent Larsen, Permits Branch (6W-PM), EPA Region 6, 1445 Ross Ave., suite 1200, Dallas, TX 75202-2733.

SUPPLEMENTARY INFORMATION:

I. Background

A draft NPDES general permit for discharge of storm water associated with industrial activity in the State of Oklahoma was noticed for public comment in the August 16, 1991, **Federal Register** (56 FR 40948). The public comment period was open from August 16, 1991, to October 15, 1991, and a public hearing was held in Oklahoma City on September 20, 1991.

As proposed, this general permit would be available to a wide range of industrial facilities in Oklahoma required to obtain a NPDES storm water discharge permit by section 402(p) of the Clean Water Act (CWA), through implementing regulations at 40 CFR 122.26. These implementing regulations were promulgated in the **Federal Register** on November 16, 1990 (55 FR 47990).

All NPDES permits are required by 40 CFR 122.44(d) and section 402 of the CWA to contain provisions necessary to insure compliance with State requirements. A condition necessary to protect rule 300.15 of the Oklahoma Water Quality Standards 1988 was inadvertently omitted from the August 16, 1991, draft general permit for Oklahoma.

II. Today's Notice

Today's notice requests public comment on an amendment to the fact sheet and draft general permit for Oklahoma published in the August 16, 1991, **Federal Register** (56 FR 40978). Only the amended general permit conditions in today's notice are open for public comment at this time.

Amendments to Fact Sheet for Draft Oklahoma General Permit

The following information is a supplement to Fact Sheet for Draft General Permit on page 40963 of the August 16, 1991, **Federal Register**. This fact sheet amendment only applies to the draft general permit for the State of Oklahoma.

The Oklahoma Water Quality Standards 1988 were adopted by the State on February 14, 1989 and approved by EPA on January 18, 1990. Rule 300.15—Limitations for Additional Protection places additional limitations on various waters of the State. New point source discharges and increased loadings from existing point source discharges are prohibited into various waters of the State designated as (1) "Outstanding Resource Waters", "Scenic River" (including waterbodies within the watersheds of such rivers), and waterbodies located within the boundaries of areas in appendix B of the 1988 Oklahoma Water Quality Standards; (2) "High Quality Waters" or (3) "Sensitive Public and Private Water Supplies". Waterbody designations are found in appendix A of the 1988 Oklahoma Water Quality Standards.

Section 502(14) of the CWA (as amended by Pub. L. 100–4) defines point source as "any discernable, confined and discrete conveyance, including but not limited to any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, rolling stock, concentrated animal feeding operation, or vessel or other floating craft, from which pollutants are or may be discharged. This term does not include agricultural storm water discharges and return flows from irrigated agriculture." Section 507 of the Water Quality Act of 1987 (Pub. L. 100–4) states "for the purposes of the Federal Water Pollution Control Act, the term "point source" includes a landfill leachate collection system." This definition is codified at 40 CFR 122.2. The definition of "storm water discharge associated with industrial activity" (codified at 40 CFR 122.26(b)(14)) is found in the November 16, 1990, **Federal Register** (55 FR 48065).

The effect of rule 300.15 of the Oklahoma Water Quality Standards 1988 is to prohibit new or increased point source discharges to certain waterbodies of the State. Some examples of new storm water point source discharges include the discharge of runoff from construction sites, new industrial facilities, or new roads. Some examples of situations that could result in increased loadings from existing storm water point source discharges include industrial plant expansion, increased fertilizer/pesticide use, removal or poor operation of existing storm water quality controls, or additional development or occupancy in industrial parks.

Parts 1.A. and 1.B. of the draft general permit for Oklahoma have been modified to further limit eligibility. In accordance with rule 300.15, the Oklahoma general permit cannot authorize a new or increased discharge to waterbodies listed under that section.

As of the date of this notice, the Oklahoma Water Resources Board is considering a change to rule 300.15 that would exempt storm water discharges. However, until and unless modified, Rule 300.15 remains in effect. Should rule 300.15 be modified before issuance of the final Oklahoma general permit, today's proposed modifications may be omitted from that final permit.

III. Modified Draft General Permit Conditions

Part I. Coverage Under this Permit

A. Permit Area

The permit covers all areas of the State of Oklahoma. However, new discharges or increased loadings from storm water associated with industrial activities, as defined at 40 CFR 122.26(b)(14), are prohibited into various waters of the State designated as (1) "Outstanding Resource Waters", "Scenic River" (including waterbodies within the Oklahoma portions of watersheds of such rivers), and waterbodies located within the boundaries of Appendix B of the 1988 Oklahoma Water Quality Standards; (2) "High Quality Waters" or (3) "Sensitive Public and Private Water Supplies". Waterbody designations are found in appendix A of the 1988 Oklahoma Water Quality Standards.

B. Eligibility

1. Except for storm water discharges identified under paragraph I.B.2. and new or increased discharges to waterbodies identified in paragraph I.A, this permit may cover all new and existing discharges composed entirely of storm water discharges associated with industrial activity.

IV. Economic Impact

An analysis of the economic impact of compliance with the draft general permit is included in the fact sheet published August 16, 1991 (56 FR 40988). Today's notice is a modification to the eligibility conditions of the draft general permit and does not change the cost estimates previously published.

VII. Executive Order 12291

The Office of Management and Budget has exempted this action from the review requirements of Executive Order 12291 pursuant to section 8(b) of that Order.

VIII. Paperwork Reduction Act

Today's notice is a modification of the draft general permit for Oklahoma published on August 16, 1991. Today's notice does not substantially change the analysis for the Paperwork Reduction Act made for the original draft general permit (56 FR 10991), which is incorporated herein by reference.

IX. Regulatory Flexibility Act

Today's notice incorporates a permit condition necessary to insure the general permit would comply with State requirements. After review of the facts presented in the notice printed above, I hereby certify, pursuant to the provisions of 5 U.S.C. 605(b), that this general NPDES permit, when issued, will not have a significant impact on a substantial number of small entities.

Joe D. Winkle,

Acting Regional Administrator, EPA Region 6.

[FR Doc. 92–9862 Filed 4–27–92; 8:45 am]

BILLING CODE 6560–50–M

FEDERAL COMMUNICATIONS COMMISSION

Applications for Consolidated Proceeding

1. The Commission has before it the following mutually exclusive applications for a new FM station:

Applicant	City/state	File No.	MM Docket No.
A. Golden Corners Broadcasting, Inc	Clemson, SC	BPH-901218MH	92-50
B. Fisher Communications of Clemson, Inc	Clemson, SC	BPH-901219MB	
C. Clemson Broadcasting, Inc	Clemson, SC	BPH-901219MD	
D. Matt Phillips, Joel Kay and Beverly Lockridge, a Partnership, d/b/a/ FM 104.9 Broadcasting	Clemson, SC	BPH-901218MD [Dismissed Herein].	

2. Pursuant to section 309(e) of the Communications Act of 1934, as amended, the above applications have been designated for hearing in a consolidated proceeding upon the issues whose headings are set forth below. The text of each of these issues has been standardized and is set forth in its entirety under the corresponding headings at 51 FR 19347, May 29, 1986. The letter shown before each applicant's name, above, is used below to signify whether the issue in question applies to that particular applicant.

Issue heading	Applicants
1. Environmental	C.
2. Air Hazard	All.
3. Comparative	All.
4. Ultimate	All.

3. If there is any non-standardized issue(s) in this proceeding, the full text of the issue and the applicant(s) to which it applies are set forth in an Appendix to this Notice. A copy of the complete HDO in this proceeding is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, D.C. The complete text may also be purchased from the Commission's duplicating contractor, Downtown Copy Center, 1114 21st Street, NW., Washington, D.C. 20036 (Telephone No. (202) 452-1422).

W. Jan Gay,

Assistant Chief, Audio Services Division, Mass Media Bureau.

[FR Doc. 92-9888 Filed 4-27-92; 8:45 am]

BILLING CODE 6710-01-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

Public Information Collection Requirements Submitted to OMB for Review

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted to the Office of Management and Budget the following public information collection requirements for review and clearance in accordance with the Paperwork Reduction Act of 1980, 44 U.S.C. chapter 35.

DATES: Comments on this information collection must be submitted on or before June 29, 1992.

ADDRESSES: Direct comments regarding the burden estimate or any aspect of this information collection, including suggestions for reducing this burden, to: the FEMA Information Collections Clearance Officer at the address below; and to Gary Waxman, Office of Management and Budget, 3235 New Executive Office Building, Washington, DC 20503, (202) 395-7340, within 60 days of this notice.

FOR FURTHER INFORMATION CONTACT: Copies of the above information collection request and supporting documentation can be obtained by calling or writing Linda Borror, FEMA Information Collections Clearance Officer, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-2624.

Type: Extension of 3067-0127.

Title: Exemption of State-Owned Properties under Self-Insurance Plan.

Abstract: Information is obtained from State and local governments to enable the Administrator, Federal Insurance Administration to determine whether a State's application meets the requirements for an exemption pursuant to section 102(c) of the Flood Disaster Protection Act of 1973. Under the Act, the FIA may grant a State having an adequate policy of self-insurance for its state-owned structures an exemption from the insurance purchase requirements of the Act. FEMA implements the provisions of the Act through its regulation published at 44 CFR 75.11-12.

Type of Respondents: State and local governments.

Estimate of Total Annual Reporting and Recordkeeping Burden: 100 Hours.

Number of Respondents: 20.

Estimated Average Burden Time per Response: 5 Hours.

Frequency of Response: Other—Upon application and when periodically reviewed.

Dated: March 6, 1992.

Wesley C. Moore,

Director, Office of Administrative Support.

[FR Doc. 92-9851 Filed 4-27-92; 8:45 am]

BILLING CODE 6718-01-M

Public Information Collection Requirements Submitted to OMB for Review

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted to the Office of Management and Budget the following public information collection requirements for review and clearance in accordance with the Paperwork Reduction Act of 1980, 44 U.S.C. chapter 35.

DATES: Comments on this information collection must be submitted on or before June 29, 1992.

ADDRESSES: Direct comments regarding the burden estimate or any aspect of this information collection, including suggestions for reducing this burden, to: the FEMA Information Collections Clearance Officer at the address below; and to Gary Waxman, Office of Management and Budget, 3235 New Executive Office Building, Washington, DC 20503, (202) 395-7340, within 60 days of this notice.

FOR FURTHER INFORMATION CONTACT: Copies of the above information collection request and supporting documentation can be obtained by calling or writing Linda Borror, FEMA Information Collections Clearance Officer, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-2624.

Type: Revision of 3067-0106.

Title: Flooded Property Purchase Program.

Abstract: Section 1362 of the National Flood Insurance Act of 1968, as amended, authorizes FEMA to purchase severely or repetitively damaged insured properties to reduce future Federal disaster costs. The information provided by communities participating in the National Flood Insurance Program and individual property owners will be used by FEMA to determine eligibility

for, funding priorities for, and cost effectiveness of the program.

Type of Respondents: Individuals or households, State and local governments, Farms, Businesses or other for-profit, Non-profit institutions, and Small businesses or organizations.

Estimate of Total Annual Reporting and Recordkeeping Burden: 225 Hours.

Number of Respondents: 165.

Estimated Average Burden Time per Response: 1.36 Hours.

Frequency of Response: Other—When homeowners or communities want to sell their severely or repetitively damaged insured properties to the FEMA.

Dated: February 28, 1992.

Wesley C. Moore,

Director, Office of Administrative Support.

[FR Doc. 92-9852 Filed 4-27-92; 8:45 am]

BILLING CODE 6718-01-M

Public Information Collection Requirements Submitted to OMB for Review

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted to the Office of Management and Budget the following public information collection requirements for review and clearance in accordance with the Paperwork Reduction Act of 1980, 44 U.S.C. chapter 35.

DATES: Comments on this information collection must be submitted on or before June 29, 1992.

ADDRESSES: Direct comments regarding the burden estimate or any aspect of this information collection, including suggestions for reducing this burden, to: the FEMA Information Collections Clearance Officer at the address below; and to Gary Waxman, Office of Management and Budget, 3235 New Executive Office Building, Washington, DC 20503, (202) 395-7340, within 60 days of this notice.

FOR FURTHER INFORMATION CONTACT: Copies of the above information collection request and supporting documentation can be obtained by calling or writing Linda Borror, FEMA Information Collections Clearance Officer, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-2624.

Type: Extension of 3067-0161.

Title: National Fire Incident Reporting System (NFIRS).

Abstract: NFIRS data is used at the local, state and Federal level, as a "standard" method of collecting information of fire incidents, which is in turn employed to quantify the National Experience and to formulate intervention strategies which target loss reduction from fire.

Type of Respondents: State and local governments, Non-profit institutions.

Estimate of Total Annual Reporting and Recordkeeping Burden: 250,000 Hours.

Number of Respondents: 14,000.

Estimated Average Burden Time per Response: 4.5 Hours.

Frequency of Response: Quarterly.

Dated: March 4, 1992.

Wesley C. Moore,

Director, Office of Administrative Support.

[FR Doc. 92-9853 Filed 4-27-92; 8:45 am]

BILLING CODE 6718-01-M

Public Information Collection Requirements Submitted to OMB for Review

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted to the Office of Management and Budget the following public information collection requirements for review and clearance in accordance with the Paperwork Reduction Act of 1980, 44 U.S.C. chapter 35.

DATES: Comments on this information collection must be submitted on or before June 29, 1992.

ADDRESSES: Direct comments regarding the burden estimate or any aspect of this information collection, including suggestions for reducing this burden, to: the FEMA Information Collections Clearance Officer at the address below; and to Gary Waxman, Office of Management and Budget, 3235 New Executive Office Building, Washington, DC 20503, (202) 395-7340, within 60 days of this notice.

FOR FURTHER INFORMATION CONTACT: Copies of the above information collection request and supporting documentation can be obtained by calling or writing Linda Borror, FEMA Information Collections Clearance Officer, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-2624.

Type: Existing Collection in Use Without OMB Control Number.

Title: Residential Basement Floodproofing Certificate.

Abstract: The Residential Basement Floodproofing Certificate provides registered engineers and architects a standard means of certifying the floodproofed construction of basements lying below the Base Flood Elevation. The homeowner is responsible for obtaining and paying for the certification and providing it to: (1) the flood insurance agent so that the homeowner receives the "discounted" insurance rate applicable to floodproofed basements; and (2) to community building officials as recognition that the basement is built according to the standards of the National Flood Insurance Program and is compliant with the communities floodplain management ordinance. The requirements for the certification are contained in a FEMA regulation published at 44 CFR 60.6(c)(2)(iv).

Type of Respondents: Individuals and households, State and local governments.

Estimate of Total Annual Reporting and Recordkeeping Burden: 192 Hours.

Number of Respondents: 60—Homeowners/Registered Architects and Engineers; 46—Communities.

Estimated Average Burden Time per Response: 3 Hours—Homeowners/Registered Architects and Engineers; 15 minutes—Communities Officials and Insurance Agents.

Frequency of Response: On occasion.

Dated: March 10, 1992.

Wesley C. Moore,

Director, Office of Administrative Support.

[FR Doc. 92-9820 Filed 4-27-92; 8:45 am]

BILLING CODE 6718-01-M

Public Information Collection Requirements Submitted to OMB for Review

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted to the Office of Management and Budget the following public information collection requirements for review and clearance in accordance with the Paperwork Reduction Act of 1980, 44 U.S.C. chapter 35.

DATES: Comments on this information collection must be submitted on or before June 29, 1992.

ADDRESSES: Direct comments regarding the burden estimate or any aspect of this information collection, including suggestions for reducing this burden, to: the FEMA Information Collections Clearance Officer at the address below; and to Gary Waxman, Office of Management and Budget, 3235 New Executive Office Building, Washington, DC 20503, (202) 395-7340, within 60 days of this notice.

FOR FURTHER INFORMATION CONTACT: Copies of the above information collection request and supporting

documentation can be obtained by calling or writing Linda Borror, FEMA Information Collections Clearance Officer, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–2624.

Type: Existing Collection in use without an OMB Control Number.

Title: Emergency Management Institute Resident Course Evaluation Form.

Abstract: Students attending the Emergency Management Institute resident program courses at FEMA's National Emergency Training Center in Emmitsburg, Maryland, complete the evaluation form at the end of each course. The information is used by EMI staff and management to identify problems with course materials, delivery, facilities, or instructors and recommend changes in course materials, student selection criteria, training experience, and classroom environment.

Type of Respondents: Individuals and households.

Estimate of Total Annual Reporting and Recordkeeping Burden: 667 Hours.

Number of Respondents: 4,000.

Estimated Average Burden Time per Response: 10 Minutes.

Frequency of Response: Other—at the completion of each course.

Dated: April 6, 1992.

Wesley C. Moore,

Director, Office of Administrative Support.

[FR Doc. 92–9821 Filed 4–27–92; 8:45 am]

BILLING CODE 6718–01–M

Public Information Collection Requirements Submitted to OMB for Review

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted to the Office of Management and Budget the following public information collection requirements for review and clearance in accordance with the Paperwork Reduction Act of 1980, 44 U.S.C. chapter 35.

DATES: Comments on this information collection must be submitted on or before June 29, 1992.

ADDRESSES: Direct comments regarding the burden estimate or any aspect of this information collection, including suggestions for reducing this burden, to: the FEMA Information Collections Clearance Officer at the address below; and to Gary Waxman, Office of Management and Budget, 3235 New Executive Office Building, Washington, DC 20503, (202) 395–7340, within 60 days of this notice.

FOR FURTHER INFORMATION CONTACT: Copies of the above information collection request and supporting documentation can be obtained by calling or writing Linda Borror, FEMA Information Collections Clearance Officer, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–2624.

Type: Existing Collection in use without an OMB Control Number.

Title: Emergency Management Institute Field Evaluation System—Course Evaluation Forms.

Abstract: Students attending the Emergency Management Institute nonresident program courses conducted by State emergency management agencies are given course evaluation forms at the beginning of the course to evaluate course content and delivery as the material is presented. The data is used by States, FEMA Regions, and the Emergency Management Institute to determine the strengths and weaknesses of EMI courses delivered in the field and to improve course design, content, instruction methods, recruitment, and administration.

Course managers at the State level must also evaluate each nonresident program course and submit to the appropriate FEMA Regional Office end-of-course evaluation packages which include the Participant Course Evaluation Forms, a Course Manager-Course Evaluation form, and a Course Evaluation Transmittal form.

Type of Respondents: Individuals and households, State and local governments.

Estimate of Total Annual Reporting and Recordkeeping Burden: 5,584 Hours.

Number of Respondents: 20,000 Students, 1,000 Course Managers.

Estimated Average Burden Time per Response: 16 minutes for students; 35 minutes for course managers.

Freqeuency of Response: Other—at the conclusion of field courses.

Dated: April 6, 1992.

Wesley C. Moore,

Director, Office of Administrative Support.

[FR Doc. 92–9822 Filed 4–27–92; 8:45 am]

BILLING CODE 6718–01–M

Public Information Collection Requirements Submitted to OMB for Review

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted to the Office of Management and Budget the following public information collection requirements for review and clearance in accordance with the Paperwork Reduction Act of 1980, 44 U.S.C. chapter 35.

DATES: Comments on this information collection must be submitted on or before June 29, 1992.

ADDRESSES: Direct comments regarding the burden estimate or any aspect of this information collection, including suggestions for reducing this burden, to: the FEMA Information Collections Clearance Office at the address below; and to Gary Waxman, Office of Management and Budget, 3235 New Executive Office Building, Washington, DC 20503, (202) 395–7340, within 60 days of this notice.

FOR FURTHER INFORMATION CONTACT: Copies of the above information collection request and supporting documentation can be obtained by calling or writing Linda Borror, FEMA Information Collections Clearance Officer, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–2624.

Type: New.

Title: National Fire Academy Extension Services Course Evaluation Form.

Abstract: The National Fire Academy (NFA) Extension Services Course Evaluation Form is used in all extension services deliveries of NFA courses. The form is used primarily to assess the effectiveness of the course materials and instructor delivery. The demographic information is used in developing needs assessments and identifying the student population's representation.

Type of Respondents: Individuals and households.

Estimate of Total Annual Reporting and Recordkeeping Burden: 5,000 Hours.

Number of Respondents: 20,000.

Estimated Average Burden Time per Response: 15 Minutes.

Frequency of Response: Other—at the completion of each course.

Dated: February 24, 1992.

Wesley C. Moore,

Director, Office of Administrative Support

[FR Doc. 92–9823 Filed 4–27–92; 8:45 am]

BILLING CODE 6718–01–M

Public Information Collection Requirements Submitted to OMB for Review

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted to the Office of Management and Budget the following public information collection requirements for

review and clearance in accordance with the Paperwork Reduction Act of 1980, 44 U.S.C. chapter 35.

DATES: Comments on this information collection must be submitted on or before June 29, 1992.

ADDRESSES: Direct comments regarding the burden estimate or any aspect of this information collection, including suggestions for reducing this burden, to: the FEMA Information Collections Clearance Officer at the address below; and to Gary Waxman, Office of Management and Budget, 3235 New Executive Office Building, Washington, DC 20503, (202) 395-7340, within 60 days of this notice.

FOR FURTHER INFORMATION CONTACT: Copies of the above information collection request and supporting documentation can be obtained by calling or writing Linda Borror, FEMA Information Collections Clearance Officer, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-2624.

Type: Revision of 3067-0208.

Title: State Administrative Plan for the Hazard Mitigation Grant Program.

Abstract: Public Law 100-707, Disaster Relief and Emergency Assistance Amendments of 1988, allows for States to apply for funding of hazard mitigation measures following a Federal declaration of a major disaster or emergency. States will serve as grantees and must prepare an administrative plan for approval by the FEMA Regional Director and plan updates after each disaster declaration which outlines their procedures for grant management.

Type of Respondents: State and local governments.

Estimate of Total Annual Reporting and Recordkeeping Burden: 148 Hours.

Number of Respondents: 20.

Estimated Average Burden Time per Response: 4 Hours.

Frequency of Response: Based on the number of 112 disasters declared over the last 3-year period (from 1989 through 1991), the average number of plan updates per State is approximately 2. Plan updates are submitted only after a disaster has been declared.

Dated: March 29, 1992.

Wesley C. Moore,

Director, Office of Administrative Support.

[FR Doc. 92-9824 Filed 4-27-92; 8:45 am]

BILLING CODE 6718-01-M

Public Information Collection Requirements Submitted to OMB for Review

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted to the Office of Management and Budget the following public information collection requirements for review and clearance in accordance with the Paperwork Reduction Act of 1980, 44 U.S.C. chapter 35.

DATES: Comments on this information collection must be submitted on or before June 29, 1992.

ADDRESSES: Direct comments regarding the burden estimate or any aspect of this information collection, including suggestions for reducing this burden, to: the FEMA Information Collections Clearance Officer at the address below; and to Gary Waxman, Office of Management and Budget, 3235 New Executive Office Building, Washington, DC 20503, (202) 395-7340, within 60 days of this notice.

FOR FURTHER INFORMATION CONTACT: Copies of the above information collection request and supporting documentation can be obtained by calling or writing Linda Borror, FEMA Information Collections Clearance Officer, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-2624.

Type: Revision of 3067-0207.

Title: Hazard Mitigation Grant Program Application.

Abstract: Public Law 100-707, Disaster Relief and Emergency Assistance Amendments of 1988 allows for States to apply for funding of hazard mitigation measures following a Federal declaration of a major disaster or emergency. States, local governments, and private non-profit organizations will be the recipients of the funds, and must meet the application requirements of 44 CFR part 206, subpart N.

Type of Respondents: State and local governments, Non-profit institutions.

Estimate of Total Reporting and Recordkeeping Burden: 4,000 Hours.

Number of Respondents: 20.

Estimated Average Burden Time per Response: 20 Hours.

Frequency of Response: FEMA estimates that each of the respondent States will submit about 10 Project Applications annually, based on the number of Federal disaster declarations. The Hazard Mitigation Grant Program is activated only after a disaster has been declared.

Dated: March 29, 1992.

Wesley C. Moore,

Director, Office of Administrative Support.

[FR Doc. 92-9825 Filed 4-27-92; 8:45 am]

BILLING CODE 6718-01-M

Public Information Collection Requirements Submitted to OMB for Review

AGENCY: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted to the Office of Management and Budget the following public information collection requirements for review and clearance in accordance with the Paperwork Reduction Act of 1980, 44 U.S.C. chapter 35.

DATES: Comments on this information collection must be submitted on or before June 29, 1992.

ADDRESSES: Direct comments regarding the burden estimate or any aspect of this information collection, including suggestions for reducing this burden, to: the FEMA Information Collections Clearance Officer at the address below; and to Gary Waxman, Office of Management and Budget, 3235 New Executive Office Building, Washington, DC 20503, (202) 395-7340, within 60 days of this notice.

FOR FURTHER INFORMATION CONTACT: Copies of the above information collection request and supporting documentation can be obtained by calling or writing Linda Borror, FEMA Information Collections Clearance Officer, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-2624.

Type: Extension of 3067-0074.

Title: Certificate of Labor Standards Compliance.

Abstract: FEMA regulation (44 CFR 308.7) requires that contractors and subcontractors comply with the Federal labor standards (29 CFR part 5) when Federal funding is provided under FEMA project grant contributions for construction of emergency operating centers and emergency communications facilities, and construction costs are in excess of $2,000. The information will be used by FEMA and State contracting agents to verify compliance and where noncompliance is found, the information will be used as the basis for nonpayment of Federal funds.

Type of Respondents: State and local governments.

Estimate of Total Annual Reporting and Recordkeeping Burden: 150 Hours.

Number of Respondents: 150.

Estimated Average Burden Time per Response: 1 Hour.

Frequency of Response: On occasion.

Dated: April 9, 1992.

Wesley C. Moore,

Director, Office of Administrative Support.

[FR Doc. 92-9826 Filed 4-27-92; 8:45 am]

BILLING CODE 6718-01-M

Public Information Collection Requirements Submitted to OMB for Review

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted to the Office of Management and Budget the following public information collection requirements for review and clearance in accordance with the Paperwork Reduction Act of 1980, 44 U.S.C. chapter 35.

DATES: Comments on this information collection must be submitted on or before June 29, 1992.

ADDRESSES: Direct comments regarding the burden estimate or any aspect of this information collection, including suggestions for reducing this burden, to: the FEMA Information Collections Clearance Officer at the address below; and to Gary Waxman, Office of Management and Budget, 3235 New Executive Office Building, Washington, DC 20503, (202) 395-7340, within 60 days of this notice.

FOR FURTHER INFORMATION CONTACT: Copies of the above information collection request and supporting documentation can be obtained by calling or writing Linda Borror, FEMA Information Collections Clearance Officer, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-2624.

Type: Existing Collection in Use Without an OMB Control Number.

Title: Federal Crime Insurance Program—Certifications, Verifications, and Claim Adjustments.

Abstract: The information collected is used by the Federal Insurance Administration's Federal Crime Insurance Program servicing company to provide day-to-day servicing of policies of crime insurance including the receipt, underwriting, processing of applications, verification of protective devices, and claim adjustments. The following forms are used with this collection: Commercial Inspection, Loss Input Report, Inspector Application, Adjuster Application, and Alarm Verification.

Type of Respondents: Individuals or households, businesses or other for-profit, non-profit institutions, and small businesses or organizations.

Estimate of Total Annual Reporting and Recordkeeping Burden: 1,081 Hours.

Number of Respondents: 8,226.

Estimated Average Burden Time per Response: 7.8 Minutes.

Frequency of Response: Other.

Dated: February 10, 1992.

Wesley C. Moore,

Director, Office of Administrative Support.

[FR Doc. 92-9827 Filed 4-27-92; 8:45 am]

BILLING CODE 6718-01-M

Public Information Collection Requirements Submitted to OMB for Review

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted to the Office of Management and Budget the following public information collection requirements for review and clearance in accordance with the Paperwork Reduction Act of 1980, 44 U.S.C. chapter 35.

DATES: Comments on this information collection must be submitted on or before June 29, 1992.

ADDRESSES: Direct comments regarding the burden estimate or any aspect of this information collection, including suggestions for reducing this burden, to: the FEMA Information Collections Clearance Officer at the address below; and to Gary Waxman, Office of Management and Budget, 3235 New Executive Office Building, Washington, DC 20503, (202) 395-7340, within 60 days of this notice.

FOR FURTHER INFORMATION CONTACT: Copies of the above information collection request and supporting documentation can be obtained by calling or writing Linda Borror, FEMA Information Collections Clearance Officer, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-2624.

Type: Revision of 3067-0170.

Title: Computerized Activities Results List (CARL).

Abstract: The Comprehensive Cooperative Agreement (CCA) is a single instrument used by the Federal Emergency Management Agency to provide Federal assistance to State and local governments for emergency management programs and activities. It is an assistance delivery vehicle intended to make it easier for States to build emergency management capabilities, address a broader range of hazards, reduce paperwork, and concentrate resources where they are most needed. As part of the CCA application process, the Computerized Activities Results List (CARL) which replaces FEMA Form 76-43, Activities Results List, is used by States to identify outputs for projects funded with CCA's and to report quarterly accomplishments. FEMA uses CARL to approve outputs, monitor progress, and verify results.

Type of Respondents: State and local governments.

Estimate of Total Annual Reporting and Recordkeeping Burden: 5,600 Hours.

Number of Respondents: 56.

Estimated Average Burden Time per Response: 20 Hours.

Frequency of Response: Annual application and quarterly.

Dated: February 11, 1992.

Wesley C. Moore,

Director, Office of Administrative Support.

[FR Doc. 92-9850 Filed 4-27-92; 8:45 am]

BILLING CODE 6718-01-M

[FEMA-940-DR]

Major Disaster and Related Determinations; Maine

AGENCY: Federal Emergency Management Agency.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Maine (FEMA-940-DR), dated March 27, 1992, and related determinations.

DATED: March 27, 1992.

FOR FURTHER INFORMATION CONTACT: Neva K. Elliott, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472 (202) 646-3614.

NOTICE: Notice is hereby given that, in a letter dated March 27, 1992, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*, Pub. L. 93-288, as amended by Pub. L. 100-707), as follows:

I have determined that the damage in certain areas of the State of Maine, resulting from heavy rains, ice jams, and flooding beginning on March 10, 1992, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act ("the Stafford Act"). I, therefore, declare that such a major disaster exists in the State of Maine.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for

Public Assistance will be limited to 75 percent of the total eligible costs.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, shall be for a period not to exceed six months after the date of this declaration.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby appoint Richard H. Strome of the Federal Emergency Management Agency to act as the Federal Coordinating Office for this declared disaster.

I do hereby determine the following areas of the State of Maine to have been affected adversely by this declared major disaster: The counties of Androscoggin, Franklin, Kennebec, Knox, Oxford, Somerset, and Waldo for Public Assistance.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance)

Wallace E. Stickney,

Director, Federal Emergency Management Agency.

[FR Doc. 92-9886 Filed 4-27-92; 8:45 am]

BILLING CODE 6718-02-M

[FEMA-941-DR]

Major Disaster and Related Determinations; Illinois

AGENCY: Federal Emergency Management Agency.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Illinois (FEMA-941-DR), dated April 15, 1992, and related determinations.

DATED: April 15, 1992.

FOR FURTHER INFORMATION CONTACT: Neva K. Elliott, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472 (202) 646-3614.

NOTICE: Notice is hereby given that, in a letter dated April 15, 1992, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*, Pub. L. 93-288, as amended by Pub. L. 100-707), as follows:

I have determined that the damage in certain areas of the State of Illinois, resulting from flooding beginning on April 13, 1992, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act ("the Stafford Act"). I, therefore, declare that such a major disaster exists in the State of Illinois.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance and Public Assistance in the designated areas. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, shall be for a period not to exceed six months after the date of this declaration.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby appoint David A. Skarosi of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the State of Illinois to have been affected adversely by this declared major disaster: The City of Chicago for Individual Assistance and Public Assistance.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance)

Wallace E. Stickney,

Director, Federal Emergency Management Agency.

[FR Doc. 92-9854 Filed 4-27-92; 8:45 am]

BILLING CODE 6718-02-M

[FEMA-936-DR]

Amendment to Notice of a Major Disaster Declaration; New Jersey

AGENCY: Federal Emergency Management Agency.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of New Jersey (FEMA-936-DR), dated March 3, 1992, and related determinations.

DATES: March 27, 1992.

FOR FURTHER INFORMATION CONTACT: Neva K. Elliott, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, D.C. 20472 (202) 646-3614.

NOTICE: The notice of a major disaster for the State of New Jersey, dated March 3, 1992, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of March 3, 1992:

Cumberland and Monmouth Counties for Public Assistance.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

Richard W. Krimm,

Deputy Associate Director, State and Local Programs and Support, Federal Emergency Management Agency.

[FR Doc. 92-9855 Filed 4-27-92; 8:45 am]

BILLING CODE 6718-02-M

[FEMA-930-DR]

Amendment to Notice of a Major Disaster Declaration; Texas

AGENCY: Federal Emergency Management Agency.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Texas (FEMA-930-DR), dated December 26, 1991, and related determinations.

DATED: April 14, 1992.

FOR FURTHER INFORMATION CONTACT: Pauline C. Campbell, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472 (202) 646-3606.

NOTICE: The notice of a major disaster for the State of Texas, dated December 26, 1991, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of December 26, 1991:

Comal County for Public Assistance (already designated for Individual Assistance).

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

Richard W. Krimm,

Deputy Associate Director, State and Local Programs and Support, Federal Emergency Management Agency.

[FR Doc. 92-9857 Filed 4-27-92; 8:45 am]

BILLING CODE 6718-02-M

FEDERAL MARITIME COMMISSION

[Docket No. 92-17]

Thai Agri Foods Co., Ltd., et. al. Asia North American Eastbound Rate Agreement; Notice of Filing and Consolidation of Complaint and Assignment

Notice is given that a complaint filed by Thai Agri Foods Co., Ltd., Thai World Export & Export Co., Ltd., Good World Company Limited, Savoy

Enterprise Ltd. Part, Tapioca Products, Ltd., United Asian Food Co., Ltd., and Tesana, Ltd. (collectively designated "Complainants") against Asia North America Eastbound Rate Agreement ("Respondent") was served April 22, 1992. Complainants allege that Respondent engaged in violations of sections 10(b), (6), (10), (11) and (12) of the Shipping Act of 1984 ("Act"), 46 U.S.C. app. 1709(b), (6), (10), (11) and (12), by entering into an invalid service contract without any meaningful service commitment, by attempting to collect deadfreight penalties for a shortfall caused by Respondent's conduct, and through its members filing independent action tariffs for rates lower than agreed upon in the service contract. Pursuant to rule 148, 46 CFR 502.148, at the request of Complainant, the complaint is consolidated with the complaints in Docket Numbers 92–06 and 92–07, because it involves substantially the same issues as these dockets.

This proceeding has been assigned to Administrative Law Judge Frederick M. Dolan, Jr. ("Presiding Officer"). Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61. The hearing shall include oral testimony and cross-examination in the discretion of the Presiding Officer only upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the Presiding Officer in this proceeding shall be issued by April 22, 1993, and the final decision of the Commission shall be issued by August 20, 1993.

Joseph C. Polking,

Secretary.

[FR Doc. 92–9781 Filed 4–27–92; 8:45 am]

BILLING CODE 6730–01–M

Ocean Freight Forwarder License Applicants; Cojan Corp., et al.

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission applications for licenses as ocean freight forwarders pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718 and 46 CFR part 510).

Persons knowing of any reason why any of the following applicants should not receive a license are requested to contact the Office of Freight Forwarders, Federal Maritime Commission, Washington, DC 20573.

Cojan Corporation, 7035 West 65th Street, Bedford Park, IL 60638, Officers: Anthony A. Coco, President/Director, Shirley E. Racine, Exec. Vice President/Director, Philip R. Carvatta, Vice President.

Allyn International Services, Inc., 17230–9 Terraverde Circle, Ft. Myers, Florida 33908, Officers: Allen R. Trevett, President, Henry S. Conrad, Jr., Vice President, Julie L. Willard, Secretary/Treasurer.

Network Trading Corp. 1316 N.W. 78th Ave., Miami, FL 33126, Officer: Luis F. Reyes, Pres./Dir./Treas./Secr.

In Joong Yoon, 333 S. Kingsley Dr., #220, Los Angeles, CA 90020, Sale Proprietor.

William H. Meadows, Inc., 6050 James S. McDonnell Blvd., Suite 13–16, Lambert Int'l. Airport, St. Louis, MO 63134–2000, Officers: William H. Meadows, President, Matthew C. Meadows, Vice President, Michael C. Meadows, Stockholder.

Action International, Inc., Miami International Airport, Bldg. #1008, Miami, FL 33152, Officers: Charles F. Edwards, President, John A. Knowles, Vice President, John R. Lucey, Stockholder, Clyde L. Hart, Vice Stockholder.

World Connections, Inc., 8341 Hindry Ave., Los Angeles, CA 90045, Officers: Mr. Marian Hirina, Vice President, John M. Hickman, Assistant Vice President, Raluca Hirina, Secretary.

Triple Freight Corp., 1850 N.W. 82nd Ave., Miami, FL 33122, Officers: Jose V. Rodriguez, President, Vincenzo Mattioli, Vice President, Roberto Rincon, Treasurer, Marlene Lopez, Secretary.

Dated: April 22, 1992.

By the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 92–9750 Filed 4–27–92; 8:45 am]

BILLING CODE 6730–01–M

Ocean Freight Forwarder License Revocations; W.J. Browning Co., Inc.

Notice is hereby given that the following ocean freight forwarder licenses have been revoked by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of ocean freight forwarders, 46 CFR 510.

License Number: 243.

Name: W.J. Browning Company, Inc.

Address: 127 Bank Street, Norfolk, VA 23510.

Date Revoked: February 14, 1992.

Reason: Failed to furnish a valid surety bond.

License Number: 1786.

Name: Max Distribution Inc.

Address: Route #28, Hawthorn, PA 16230.

Date Revoked: March 20, 1992.

Reason: Failed to furnish a valid surety bond.

License Number: 2428

Name: Bekins Moving & Storage Co., Inc. dba Northwest Forwarders.

Address: 9401 Aurora Ave., So. Seattle, WA 98103.

Date Revoked: April 13, 1992.

Reason: Surrendered license voluntarily.

Bryant L. VanBrakle,

Director Bureau of Tariffs, Certification and Licensing.

[FR Doc. 92–9755 Filed 4–27–92; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

[Docket No. R-0757]

Treatment of U.S. Companies Operating in Government Debt Market in France

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice of study and request for comment.

SUMMARY: Under the Primary Dealers Act of 1988, which became effective in August, 1989, the Federal Reserve may not designate or permit the continuation of the designation as a primary dealer of any person of a foreign country if that person's home country does not grant to U.S. companies the same competitive opportunities in the underwriting and distribution of government debt instruments issued by such country as such country accords to its domestic companies. Pursuant to this Act, the Federal Reserve is reviewing the government debt market of France and requests public comment on the treatment of U.S. companies with respect to the French government debt market, focusing in particular on the treatment of U.S. companies relative to domestic firms.

EFFECTIVE DATE: Comments must be received by June 25, 1992.

ADDRESSES: Comments, which should refer to Docket No. R-0757, may be mailed to Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW., Washington,

DC 20551, to the attention of Mr. William W. Wiles, Secretary. Comments addressed to the attention of Mr. Wiles may be delivered to the Board's mailroom between 8:45 a.m. and 5:15 p.m., and to the security control room outside of those hours. Both the mailroom and the security control room are accessible from the courtyard entrance on 20th Street between Constitution Avenue and C Street, NW. Comments may be inspected in room B-1122 between 9 a.m. and 5 p.m., except as provided in § 261.8 of the Board's Rules Regarding the Availability of Information, 12 CFR 261.8.

FOR FURTHER INFORMATION CONTACT: Kathleen O'Day, Assistant General Counsel (202/452-3786), or Deborah Burand, Senior Attorney (202/452-3427), Legal Division; John Montgomery, Economist (202)/452-3579), or Larry Promisel, Senior Associate Director (202/452-3533), Division of International Finance; Board of Governors of the Federal Reserve System. For the hearing impaired *only*, Telecommunication Device for the Deaf (TDD), Dorothea Thompson (202/452-3544), Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW., Washington, DC 20551.

SUPPLEMENTARY INFORMATION: Under the Primary Dealers Act of 1988 (Act), 22 U.S.C. 5341-5342, the Federal Reserve may not permit a person of a foreign country to act as a primary dealer in U.S. government securities if the person's home country does not accord U.S. companies the same competitive opportunities as the foreign country accords domestic companies in underwriting and distributing government debt obligations of such foreign country. A "person of a foreign country" includes any foreign individual or company that directly or indirectly controls a primary dealer.

In connection with a proposed transaction, a French company is expected to acquire indirect control of a primary dealer in U.S. government securities. Accordingly, in order to make the determination required by the Act, the Federal Reserve is undertaking a study of the government debt market of France to determine whether U.S. companies are accorded national treatment in their access to that market.

The Federal Reserve would welcome the views of U.S. firms or other persons on the specific respects in which U.S. companies are accorded, or are not accorded, the same competitive opportunities in the underwriting and distribution of French government debt instruments as France accords to French domestic companies. All such comments, which should be submitted by June 25, 1992, would be considered in the context of the study of this market.

By order of the Board of Governors of the Federal Reserve System, April 21, 1992.

William W. Wiles,

Secretary of the Board.

[FR Doc. 92-9818 Filed 4-27-92; 8:45 am]

BILLING CODE 6210-01-F

Edwards Brothers Holding Co., Inc.; Formation of, Acquisition by, or Merger of Bank Holding Companies

The company listed in this notice has applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that application or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Comments regarding this application must be received not later than May 22, 1992.

A. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. Edwards Brothers Holding Company, Inc., Denton, Montana; to become a bank holding company by acquiring 100 percent of the voting shares of Farmers State Bank of Denton, Denton, Montana.

Board of Governors of the Federal Reserve System, April 22, 1992.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 92-9793 Filed 4-27-92; 8:45 am]

BILLING CODE 6210-01-F

Randolph W. Lenz, et al.; Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than May 18, 1992.

A. Federal Reserve Bank of Boston (Robert M. Brady, Vice President) 600 Atlantic Avenue, Boston, Massachusetts 02106:

1. Randolph W. Lenz, Fort Lauderdale, Florida; to acquire at least 83.42 percent of the voting shares of Amity Bancorp, Inc., New Haven, Connecticut, and thereby indirectly acquire Amity Bank, Woodbridge, Connecticut.

B. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. Ralph Moody Hall, Rockwall, Texas; to acquire an additional 11.10 percent, for a total of 19.22 percent, of the voting shares of Lakeside Bancshares, Inc., Rockwall, Texas, and thereby indirectly acquire Lakeside National Bank, Rockwall, Texas.

2. James P. Leake, Dallas, Texas; to acquire 89.74 percent of the voting shares of Bandera Bancshares, Inc., Bandera, Texas, and thereby indirectly acquire Bandera Bank, Bandera, Texas.

Board of Governors of the Federal Reserve System, April 22, 1992.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 92-9794 Filed 4-27-92; 8:45 am]

BILLING CODE 6210-01-F

Regional Bancshares, Inc.; Application to Engage de novo in Permissible Nonbanking Activities

The company listed in this notice has filed an application under § 225.23(a)(1)

of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than May 22, 1992.

A. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. Regional Bancshares, Inc., Alton, Illinois; to engage *de novo* through its subsidiary, Bank of Alton, Alton, Illinois, in receiving commission income from the sale of credit life insurance policies issued on loans, pursuant to § 225.25(b)(8)(i) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, April 22, 1992.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 92-9795 Filed 4-27-92; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Human Services Transportation Technical Assistance Project

Pursuant to section 1110 of the Social Security Act, the Assistant Secretary for Planning and Evaluation and the Director of the Office of Intergovernmental Affairs (IGA) of the Department of Health and Human Services (HHS) are seeking applications for technical assistance in the area of human services transportation from national organizations with a record of assisting rural and special transportation needs.

DATES: The closing date for submittal of applications under this announcement is June 12, 1992.

ADDRESSES: An application kit may be requested from: HHS/IGA, 200 Independence Avenue, SW., room 621-E, Washington, DC 20201, telephone: (202) 245-6036.

APPLICATION RECEIPT POINT: Department of Health and Human Services, ASPE/IO, 200 Independence Avenue, SW., room 426-F, Washington, DC 20201. Attn: Al Cutino.

FOR FURTHER INFORMATION CONTACT: Dianne L. McSwain, HHS/IGA, 200 Independence Avenue, SW., room 621-E, Washington, DC 20201, telephone: (202) 245-6036. Questions may be faxed to (202) 245-5672 (applications may not be faxed for submission).

AWARD INFORMATION: This announcement solicits applications and describes the application process for the award of the cooperative agreement(s). It is the intent of HHS to fund at least one project, and possibly several projects, which address the various task areas in this announcement. The project period will be for one year. There is no intent to provide additional funding for this effort beyond the twelve-month project period described herein.

Part I. General Information

Legislative Authority

The Transportation Coordination Technical Assistance Project cooperative agreement(s) are authorized by Section 1110 of the Social Security Act (42 U.S.C. 1310) and awards will be made from funds appropriated under Public Law 102-170 (DHHS Appropriation Act for FY 1992).

Project History and Purpose

In FY 1990, Congress authorized $250,000 for the provision of technical assistance to human service transportation providers. This effort included the compilation of data on specific target populations, the development of mechanisms for dissemination of information, and the preparation of a report to the Secretary on the provision of transportation services to human service clients. For FY 1991, the Congress authorized $500,000 for this effort, adding funding for specific technical assistance in the implementation of the requirements of the Americans with Disabilities Act (ADA). For FY 1992, the Congress has again authorized $500,000 for continued technical assistance in human services transportation.

The purpose of this announcement is to solicit applications for the provision of technical assistance to those organizations, agencies and individuals involved in the planning and provision of human services transportation to the clients of HHS-funded programs. This announcement represents a follow-on activity to the effort funded in FY 1991.

It is the policy of HHS to coordinate related programs at the Federal level wherever possible and to promote maximum feasible coordination at the State and local level. Coordination and collaborative effort maximize the resources available to address specific needs. Reflecting this policy, HHS and the DOT have established the Joint DHHS/DOT Coordinating Council on Human Services Transportation (Coordinating Council) as a focal point for the effort to coordinate HHS and DOT resources for transportation of HHS program client populations. The goals of the Coordinating Council are as follows:

(1) To achieve the most cost-effective use of Federal, State and local resources for specialized and human services transportation;

(2) To encourage State and local governments to take a more active role in the management and coordination of programs supporting specialized and human services transportation;

(3) To adopt administrative and management practices in the implementation of Federal programs which encourage coordination among service providers and increase access to specialized and human services transportation;

(4) To share technical resources and information with recipients of Federal assistance and transportation providers; and

(5) To encourage the most efficient system of providing services, including consideration of private sector providers and use of competitive bidding.

In support of these goals, HHS has identified the following objectives for the Human Services Transportation Technical Assistance Project:

(1) To promote more efficient use of equipment, facilities, and staff resources at the State local level;

(2) To provide information, technical data, and assistance to State and local agencies to improve management of transportation services and the acquisition of appropriate equipment and facilities; and

(3) To develop information and technical data on the use of transportation resources by human services clientele.

Applicants should reflect an understanding of these goals and objectives in their applications.

Available Funds

HHS intends to award one or more cooperative agreements resulting from this announcement. The size of the awards will vary depending on the level of effort proposed and the requirements of HHS in meeting the technical assistance needs of the providers of human services transportation. HHS anticipates awarding approximately $490,000 in cooperative agreement(s).

Period of Performance

The start-up date of the project will be July 1, 1992 for a project period of 12 months under this announcement.

Part II. Human Services Transportation Technical Assistance Project—Responsibilities of the Awardees and the Federal Government

Awardee Responsibilities

The Human Services Technical Assistance project requires the development and maintenance of mechanisms to provide information, technical assistance, and training to HHS human services transportation planners and providers on the efficient use of transit resources, equipment and facilities. Applicants should be aware of and be sensitive to the need to coordinate the activities herein with the activities of the Rural Transit Assistance Program (RTAP) funded through the Federal Transit Administration (FTA) of the Department of Transportation (DOT) and the Eldercare Institute on transportation funded through the Administration on Aging, HHS.

The following task are to be specifically addressed in the project narrative of the application. Applicants are encouraged to be innovative and to suggest additional subtasks that may improve the potential for successful completion of the task. However, applicants are cautioned to provide suggestions for additional subtasks judiciously with concern for the overall cost of the project. There will be no additional funds beyond those appropriated by Congress for this project.

Task I: Project Planning and Coordination

Task I entails the preparation of a detailed work plan of the activities proposed to meet the stated objectives of the project, including monthly meetings with the federal project staff and a final report due at the end of the project period. The work plan provides detailed descriptions of task activities and specific time frames for the accomplishment of the activities in measurable terms and reflects consultation with the Federal Project Officer (FPO).

Task II: Development of Human Services Transportation Resource Center

Task II addresses the development and maintenance of a central repository of information and technical assistance materials for developing or improving coordinated transportation systems (hereafter known as the Resource Center). Access to the Resource Center should be available to State and local human service agencies, planning entities, government decision-makers and transportation service providers. The Resource Center will be the focal point for the ongoing collection and dissemination of information on issues of specific concern to human services transportation planners and providers as the issues evolve. A priority of the Resource Center will be the support of regional, State or local groups that seek to improve coordination of human services transportation.

The Resource Center will contain, at a minimum, federal- and State-produced technical assistance and training materials, federal human service transit-related legislation and regulations, training and technical assistance materials that will be developed through this effort, and other relevant materials as identified by HHS, a the Coordinating Council, or the awardee.

Activities that might be undertaken to accomplish this task include:

(1) Providing ready access to the technical assistance and information of the Center such as through the use of "hotlines" and electronic bulletin boards;

(2) Developing a mechanism for screening requests for technical assistance which will identify the appropriate level and type of technical assistance, such as immediate telephone response, research and compilation of a written response, practitioner network assistance by telephone, in writing, or through an on-site visit (see Task IV);

(3) Developing and maintaining a calendar of meetings, conferences and other events that would be of interest to the human services transportation field;

(4) Developing procedures to ensure that organizations or individuals obtain requested materials or information in a timely manner (Applicants are encouraged to disseminate information through links with other agencies rather than attempting to store and disseminate documents);

(5) Identifying, tracking and coordinating activities of other major national or regional organizations interested in human services transportation with activities; and

(6) Compiling information on the usage of the clearinghouse and hotline, including but not limited to the data on the rate of use, kinds of inquiries, and types of requesting organizations to be included in the monthly projects meetings.

Task III: Development and Coordination of a Resource Network of Knowledgeable Practitioners of Human Services Transportation

Task III represents the establishment and coordination of a network of identified, certified practitioners in the field of human services transportation that can be made available to transportation planners or providers by telephone or, when appropriate, by on-site visit.

The following activities at a minimum, might be undertaken to complete this task:

(1) Develop a set of criteria against which practitioners may be certified,

(2) Develop and implement a plan to identify practitioners for certification,

(3) Develop a mechanism for screening requests for technical assistance which will identify the need for practitioner assistance and will then identify whether that assistance can be provided by telephone, in writing, or if an on-site visit is warranted, and

(4) Develop a written format for reporting practitioner contacts so that the information can be reviewed for inclusion in the Resource Center.

Task IV: Disseminate Information on the Provision of Human Services Transportation

Task IV addresses the dissemination of the information compiled through the Resource Center activities, information

accumulated under Task III, and information that the federal government deems necessary for distribution to the human services transportation network. The dissemination of information and materials relating to the implementation of the ADA transportation requirements is of priority under this task.

Project dissemination activities under Task IV will be coordinated with those of regional, State and human services transportation coordination efforts to avoid duplication of efforts and to construct complementary and mutually beneficial activities.

At a minimum the awardee would be expected to undertake the following activities in support of Task IV:

(1) Identifying opportunities to disseminate information through the existing publications of relevant human services organizations on issues of interest to the human services transportation community (a minimum of 12 articles during the project period);

(2) Identifying and coordinating through the practitioner network requests for conveners and facilitators for regional, State and local-level groups and forums;

(3) Identifying, tracking and coordinating activities of other major national or regional organizations interested in human services transportation with activities planned under this project including identifying opportunities to participate in National or regional conferences (present at a minimum of 15 human services meetings);

(4) Planning, organizing and presenting training conferences on coordination and ADA implementation issues (a minimum of five regional meetings);

(5) Developing and disseminating a formal introduction package to the resources available through the project and the Resource Center including the dissemination of a basic information package on the Resource Center through the Head Start, Aging, Medicaid transportation, and Social Security Field Office networks.

Task V: Other Activities Identified by the Government Project Officer

HHS anticipates that from time to time other activities related to the scope of effort described in this announcement and the work of the Coordinating Council will be identified by the FPO. In past years these activities have included short term comparison studies of the use of Transportation at specific Head Start sites and the use of Medicaid funds by a sample of States in funding transportation. These activities will represent no more than 15% of the entire project effort and will be negotiated with the awardee in context with the other activities under way at the time of request.

Federal Government Cooperative Agreement Responsibilities

HHS or its representatives will provide:

(1) Consultation and technical assistance in planning, operating, and evaluating the technical assistance activities of the project;

(2) Up-to-date information on federal government regulations identified as affecting the provision of transportation services to human service clients;

(3) Assistance in the evaluation of project effectiveness;

(4) Assistance in collaborating with appropriate State and local governmental entities in the performance of the project activities;

(5) Assistance in the identification of HHS information and technical assistance resources pertinent to the success of this project; and

(6) Assistance in the transfer of "successful practices" in the human services transportation to other Federal, State and local entities.

Part III. Application Preparation and Evaluation Criteria

The part contains information on the preparation of an application for submission under this announcement, the forms necessary for submission and the evaluation criteria under which the applications will be reviewed. Potential applicants should read this part carefully in conjunction with the information provided in Part II.

To ensure that organizations with the greatest capacity for providing quality services participate in this effort, applicants for funding under the announcement should reflect, in the program narrative section of the application, how they will be able to fulfill the responsibilities and requirements described in this section of the announcement. Applicants may choose to address all the identified tasks, Tasks I through IV, or Tasks I and V. Applicants may choose to address any or all of these options, however, each option addressed must include a separate budget plan. All applications must address Task 1. HHS reserves the right to award the entire effort to one organization or to separate the effort into multiple projects depending on the scope and quality of the submissions. It is the intent of HHS to make sufficient awards as to accomplish the entire scope of effort described in this announcement, if submissions of sufficient scope and quality are received to permit it.

The applicant should include: (1) A management plan, which sets forth how the project will be managed and who will be the key personnel involved, including a Gantt chart and other graphics which specifically display the management information provided in text; and (2) a budget plan, which specifically delineates the costs associated with the project. When the applicant chooses to suggest additional efforts to support a task, the cost of those additional efforts (not required by this announcement) should be separately identified. However, at no time will a proposed budget in excess of $490,000 for all the Tasks listed in the Solicitations be considered for funding, unless the amount in excess of $490,000 represents grantee cost-sharing.

Review Process and Funding Information

Applications that are submitted by the deadline date and which meet the screening criteria will be reviewed and scored competitively. The applications will be reviewed using the evaluation criteria listed below to score the applications. These review results will be a primary factor in funding decisions.

HHS reserves the option to discuss applications with other Federal agencies, Central or Regional Office staff, specialists, experts, States and the general public. Comments from these sources, along with those of the reviewers, will be considered in making funding decisions.

State Single Point of Contact (E.). No. 12372)

The Department of Health and Human Services has determined that this program is not subject to Executive Order No. 12372, Intergovernmental Review of Federal Programs, because it is a program that is national in scope and the only impact on State and local governments would be through subgrants. Applicants are not required to seek intergovernmental review of their applications within the constraints of E.O. No. 12372.

Deadline for Submittal of Applications

The closing date for submittal of applications under this announcement is June 12, 1992. Applications must be postmarked or hand-delivered to the application receipt point no later than 5 p.m. on June 12, 1992.

Hand-delivered applications will be accepted Monday through Friday prior to and on June 12, 1992, during the working hours of 9 a.m. to 5 p.m. in the

lobby of the Hubert H. Humphrey building located at 200 Independence Avenue, SW., in Washington, DC. When hand-delivering an application, call (202) 245-1794 from the lobby for pick up. A staff person will be available to receive applications.

An application will be considered as meeting the deadline if it is either: (1) Received at, or hand-delivered to, the mailing address on or before June 12, 1992, or (2) Postmarked before midnight of the deadline date, June 12, 1992, and received in time to be considered during the competitive review process (within two weeks of the deadline date).

When mailing application packages, applicants are strongly advised to obtain a legibly dated receipt from a commercial carrier (such as UPS, Federal Express, etc.) or from the U.S. Postal Service as proof of mailing by the deadline date. If there is a question as to when an application was mailed, applicants will be asked to provide proof of mailing by the deadline date. When proof is not provided, an application will not be considered for funding. Private metered postmarks are not accepted as proof of timely mailing.

Applications which do not meet the June 12, 1992, deadline are considered late applications and will not be considered or reviewed in the current competition. HHS will send a letter to this effect to each late applicant.

HHS reserves the right to extend the deadline for all applications due to acts of God, such as floods, hurricanes or earthquakes; due to acts of war; if there is widespread disruption of the mail; or if HHS determines a deadline extension to be in the best interest of the Government. However, HHS will not waive or extend the deadline for any applicant unless the deadline is waived or extended for all applicants.

Application Requirements

Applicants are advised to read and follow this section very carefully. Applicants which do not meet these initial requirements may not be considered or reviewed in the competition, and the applicant will be so informed. A complete and conforming application must meet the following requirements:

Eligible applicants are national organizations or large institutions with a record of assisting rural and special transportation needs.

Application Forms

See section entitled "Components of a Complete Application". All of these documents must accompany the application package.

Maximum Length

No specific limit will be set for the length of the application. However, applications that are overly long and/or contain superfluous material will be viewed as indicating an inefficient approach.

Evaluation Criteria

The evaluation criteria correspond to the outline for the development of the Program Narrative Statement of the application. Although not mandatory, it is strongly recommended that applications be prepared with the format indicated by this outline.

Applications which meet the initial requirements will be reviewed by a panel of at least three reviewers. Reviewers will determine the strengths and weaknesses of each application in terms of the evaluation criteria listed below, provide comments and assign numerical scores. The point value following each criterion heading indicates the maximum numerical weight that each section will be given in the review process.

1. Understanding of the Effort

The application discusses in detail the applicant's understanding of the need for the project, the background and evolution of the effort to coordinate human services transportation, the significant participants in the coordination effort and the specific relevance of the proposed Tasks to the identified need. The application relates the project to the goals and objectives described in the first section of this announcement. 10 points

2. Project Approach

The application outlines a sound and workable approach to the effort and details how the proposed tasks will be accomplished; cites factors which might accelerate or decelerate the work, giving acceptable reasons for taking this approach as opposed to others; describes and supports any unusual features of the project, such as design or technological innovations, reductions in cost or time, or extraordinary collaborative involvements; and provides for projections of the accomplishments to be achieved. It lists the activities to be carried out in chronological order, showing a reasonable schedule of accomplishments and target dates.

To the extent applicable, the application identifies the kinds of data to be collected and/or maintained, and discusses the criteria to be used to evaluate the results and successes of the project. It describes the evaluation methodology that will be used to determine if the needs identified and discussed are being met and if the results and benefits identified are being achieved. The application also lists each organization, agency, consultant, or other key individuals or groups who will work on the project, along with a description of the activities and nature of their effort or contribution. 25 points

3. Staffing Utilization, Staff Background and Experience

The application identifies the background of the principal project staff members. The name, address, training, educational background, and other qualifying experience are provided for the project director and the key project staff. Any staff to be added as a result of the award of this Cooperative agreement should be clearly delineated. The applicant provides assurance that the proposed staff will be available to work on the project effort upon award of the cooperative agreement. The principal author of the application is identified and that person's role in the project is identified. 25 points

4. Organizational Experience

The application identifies the qualifying experience of the organization to demonstrate the applicant's ability to effectively and efficiently administer this project. The application specifically identifies the applicant as a national organization or large institution with a record of assisting rural and special transportation needs. Previous specific experience with work similar to the Tasks proposed is clearly and specifically described. The relationship between this project and other work planned, anticipated, or underway by the applicant is described, including a chart which lists all related Federal assistance received within the last five years. The previous Federal assistance is identified by project number, Federal agency, and grants or conducting officer. 40 points

Components of a Complete Application

1. A complete application consists of the following items in this order:

Application for Federal Assistance (Standard Form 424, REV 4-88);

2. Budget Information—Non-construction Programs (Standard form 424A, REV 4-88);
3. Assurances—Non-construction Programs (Standard Form 424B, REV 4-88);
4. Table of Contents;
5. Budget justification for Section B-Budget Categories;

6. Proof of non-profit status, if appropriate;
7. Copy of the applicant's approved indirect cost rate agreement, if necessary;
8. Project Narrative Statement, organized in four sections addressing the following areas:
   (a) Understanding of the Effort,
   (b) Project Approach,
   (c) Staffing Utilization, Staff Background, and Experience
   (d) Organizational Experience;
9. Any appendices/attachments;
10. Certification Regarding Drug-Free Workplace;
11. Certification Regarding Debarment, Suspension and Other Responsibility Matters; and
12. Certification and, if necessary, Disclosure Regarding Lobbying.
13. Supplement to Section II—Key Personnel.
14. Application for Federal Assistance Checklist.

Dated: April 20, 1992.

Martin H. Gerry

Assistant Secretary for Planning and Evaluation.

[FR Doc. 92-9815 Filed 4-27-92; 8:45 am]

BILLING CODE 4150-04-M

Federal Council on the Aging; Meeting

Agency Holding the Meeting: Federal Council on the Aging.

Time and Date: Meeting begins at 9 a.m. and ends at 4:30 p.m. on Wednesday, May 13, 1992, and begins at 9 a.m. and ends at 4:30 p.m., on Thursday, May 14, 1992.

Place: On Wednesday, May 13, from 9 a.m. to 12 noon, and from 1:30 p.m. to 4:30 p.m., in the Snow Room, Fifth Floor—room 5051, Wilbur J. Cohen Building, 330 Independence Avenue, SW., Washington, DC. On Thursday, May 14, from 9 a.m. to 12 noon, and from 1:30 p.m. to 4:30 p.m., in the Snow Room, Fifth Floor—room 5051, Wilbur J. Cohen Building, 330 Independence Avenue, SW., Washington, DC.

Status: Meeting is open to the public. (Due to building security, names of attendees should be called into FCoA office (619-2451) prior to meeting dates).

Contact Person: Kevin W. Parks, rm. 4280, Wilbur J. Cohen Building, 330 Independence Ave., SW., Washington, DC 20201 (202) 619-2451.

The Federal Council on the Aging was established by the 1973 Amendments to the Older Americans Act of 1965 (Pub.L. 93-29, 42 U.S.C. 3015) for the purpose of advising the President, the Secretary of Health and Human Services, the Commissioner on Aging and the Congress on matters relating to the special needs of older Americans.

Notice is hereby given pursuant to the Federal Advisory Committee Act (Pub.L. 92-453, 5 U.S.C. app. 1, Sec. 10, 1976) that the Council will hold its third quarterly meeting of FY 92 on May 13 and 14, 1992, from 9 a.m. to 4:30 p.m. respectively. On May 13 and 14, the meeting will be held in the Snow Room, Fifth Floor—room 5051, Wilbur J. Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201-0001.

The Agenda Will Include: On Wednesday, May 13th, the morning session will be devoted to the Council's regular business session. The afternoon session will include remarks from various officials or staff representatives from the Department of Health & Human Services, including Dr. Sambhu N. Banik, Ph.D., Executive Director, President's Committee on Mental Retardation, and officials of the Indian Health Service. On Thursday, May 14th at 2 p.m., remarks by Dr. Joyce T. Berry, Commissioner, U.S. Administration on Aging.

The rest of the two-day meeting will be devoted to discussion of FCoA subcommittee meetings and reports, discussion of presentations and formulation of recommendations, and other matters as they relate to the aging population.

Dated: April 22, 1992.

Ingrid C. Azvedo,

Chairman, Federal Council on the Aging.

[FR Doc. 92-9816 Filed 4-27-92; 8:45 am]

BILLING CODE 4130-01-M

Agency for Toxic Substances and Disease Registry

[ATSDR-49]

Presolicitation Notice for Great Lakes Research Applications

Purpose of Notice

This notice is to alert health departments, educational institutions, and research institutions of state, local and tribal governments of the Great Lakes region that a solicitation for applications will be published approximately May 15, 1992. The Agency for Toxic Substances and Disease Registry (ATSDR) will be seeking applicants for grants to conduct research on the human health impact of consumption of contaminated fish in the Great Lakes region.

Background

The Great Lakes basin contains a major part of the U.S. industrial and agricultural activity. The physical nature of the basin and the long retention time of the Lakes combine to make this huge freshwater resource a repository for chemical byproducts of these production activities. Through the process of bioaccumulation, these pollutants are taken up by aquatic life and become especially concentrated in Great Lakes game fish, among other wildlife. Several persistent toxic substances appear to be predominant in the Great Lakes: PCB's, DDT and its metabolites, dieldrin, toxaphene, mirex, mercury, benzo[a]pyrene, hexachlorobenzene, furans, dioxins, and lead. Associations between the consumption of contaminated Great Lakes fish and long-term adverse health effects have been demonstrated in certain populations.

Authorization and Appropriation

In the FY 1992 appropriation for the ATSDR, approximately $2,000,000 is specified by committee language for ATSDR to support research for a study of the human health impacts of eating contaminated fish. Continuation of this research program beyond the first year is contingent upon the subsequent availability of funds. Section 104(i)(15) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA) (42 U.S.C. 9604(i)(15)), authorizes ATSDR to provide assistance for such health studies to states and political subdivisions thereof. Section 104(i)(5)(A) of CERCLA, as amended (42 U.S.C. 9604(i)(5)(A)), requires ATSDR to assure the initiation of a research program to fill priority data needs associated with hazardous substances. The ATSDR Great Lakes research program may also serve to fill substance-specific data needs in this program.

Eligible Applicants

Eligible applicants are the Great Lakes States which include: Illinois, Indiana, Michigan, Minnesota, Ohio, Pennsylvania, New York and Wisconsin; and political subdivisions thereof, which may include state universities, state colleges, state research institutions, and state and local health departments, and federally recognized Indian Tribes. This is consistent with section 106, subsection 118(e) of the Great Lakes Critical Programs Act of 1990 (33 U.S.C. 1268(e)(3)). ATSDR encourages collaborative efforts among these potential applicants.

Project Period and Research Activities

Awards will be for a 12-month budget period with a proposed project duration

of 1 to 3 years. Certain target groups, e.g., Native Americans, and fetuses and nursing infants of mothers who consume contaminated Great Lakes fish, have been demonstrated to have a higher risk of long-term adverse effects resulting from exposure to these contaminants. ATSDR anticipates that research proposals will focus on these high risk populations. The eligible research activities shall include but not be limited to:

1. Determining the profiles and levels of Great Lake's toxicants in human biological tissues and fluids;
2. Identifying sensitive and specific human reproductive/developmental endpoints and correlating them to exposure to Great Lake's toxicants;
3. Determining the short- and long-term risk(s) of adverse health effects in progeny which result from parental exposure to Great Lake's toxicants (special emphasis on reproductive/developmental, behavioral, neurological, and endocrinological endpoints);
4. Investigating the feasibility of establishing a registry of exposed persons and/or surveillance cohorts in the Great Lakes region; and
5. Establishing a chemical mixture's database in order to identify new cohorts, conduct surveillance and health effects studies, and establish subregistries of exposed individuals and/or surveillance cohorts.

In awarding grants pursuant to the Great Lakes Critical Programs Act, ATSDR shall consider proposed projects that will help fill information gaps and address research needs regarding the human health impact of consumption of contaminated fish from the Great Lakes.

When and Where to Obtain Applications

A formal program announcement (Number 215) describing in detail the application requirements will be published in the **Federal Register** on approximately May 15, 1992. The announcement will describe the information to be included in applications and other information needed to permit ATSDR to assess the merit of proposed research projects. The contact for requesting a copy of the application kit after the program announcement has been published is: Van Malone, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, NE., room 300D, Mailstop E-14, Atlanta, Georgia 30305, Telephone: (404) 842-6797.

Please refer to Announcement Number 215 when requesting information.

Dated: April 22, 1992.

William L. Roper,

Administrator, Agency for Toxic Substances and Disease Registry.

[FR Doc. 92-9790 Filed 4-27-92; 8:45 am]

BILLING CODE 4160-70-M

National Institutes of Health

National Cancer Institute; Workshop/Discussion on Strategies for Training Cancer Researchers in the 90s

Notice is hereby given of a workshop/discussion entitled "Strategies for Training Cancer Researchers in the 90s" by the National Cancer Institute, Division of Cancer Biology, Diagnosis, and Centers, June 10, 1992, in Building 31C, Conference Room 7, National Institutes of Health, Bethesda, Maryland 20892.

The workshop/discussion will be open to the public from 8:30 a.m. to 12 noon. Attendance by the public will be limited to space available.

For further information, contact Dr. Vincent Cairoli, Cancer Training Branch, National Cancer Institute, Executive Plaza North, room 232, Bethesda, Maryland, 20892, (301) 496-8580.

Dated: April 21, 1992.

Bernardine Healy,

Director, NIH.

[FR Doc. 92-9785 Filed 4-27-92; 8:45 am]

BILLING CODE 4140-01-M

National Heart, Lung, and Blood Institute; Meeting

Notice is hereby given of the meeting of the National Heart Attack Alert Program Coordinating Committee, sponsored by the National Heart, Lung, and Blood Institute on Friday, June 12, 1992, from 8:30 a.m. to 3 p.m., at the Hyatt Regency Bethesda Hotel, 1 Bethesda Metro Center, Bethesda, Maryland, 20814 (301) 657-1234. The entire meeting is open to the public. The Coordinating Committee is meeting to discuss the progress of the National Heart Attack Alert Program with its participating organizations.

Attendance by the public will be limited to space available.

For detailed program information, agenda, list of participants, and meeting summary, contact: Ms. Mary McDonald, Coordinator, of the National Heart Attack Alert Program, Health Education Branch, Office of Prevention, Education, and Control, National Heart, Lung, and Blood Institute, National Institutes of Health, Building 31, room 4A16, Bethesda, Maryland 20892, (301) 496-1051.

Dated: April 20, 1992.

Bernadine Healy,

Director, NIH.

[FR Doc. 92-9786 Filed 4-27-92; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). Copies of the proposed information collection and related forms and explanatory material may be obtained by contacting the Bureau's clearance officer at the phone number listed below. Comments and suggestions on the requirement should be made directly to the Bureau clearance officer and to the Office of Management and Budget Interior Desk Officer, Washington, DC 20503, telephone 202-395-7340.

Title: Indian Revolving Loan Fund and Loan Guaranty and Insurance Fund Applications and Requirements (25 CFR parts 101 and 103)

OMB Approval Number 1076-0020.

Abstract: The information being requested relates to credit-worthiness of borrowers and potential for success of businesses on Indian reservations for which loans or loan guarantees have been requested. Information will be used to decide the potential for loan repayment and enhancement of Indian reservation economies. Information will also be used for loan servicing and decision when technical assistance to a business is needed. Indian tribes and individuals will be affected.

Bureau Form Numbers: BIA Forms 4706, 4729, 4737, 4738, 4739, 4740, 4741, 4745, 4753, 4755, 4759, and 4760.

Frequency: On occasion.

Description of Respondents: Indian tribes, Indian organizations, and Indian individuals.

Estimated Completion Time: An average of 36 minutes per form.

Annual Responses: 1657.

Annual Burden Hours: 985.

Bureau Clearance Officer: Gail Sheridan 202-208-2685.

Dated: January 21, 1992.

Patrick A. Hayes,

Director, Office of Trust and Economic Development.

[FR Doc. 92-9766 Filed 4-27-92; 8:45 am]

BILLING CODE 4310-02-M

Bureau of Land Management

[NV-050-91-4320-02]

Las Vegas District Advisory Council; Meeting

AGENCY: Bureau of Land Management, Department of the Interior Notice is hereby given in accordance with Public Law 920463 that a meeting of the Bureau of Land Management, Las Vegas District Advisory Council will be held May 15, 1992, at 9 a.m. to 3 p.m. in the Las Vegas BLM District Office, Las Vegas, Nevada.

The meeting agenda will include:

1. Status Report: Desert Tortoise Recovery Plan.
2. Draft of Resource Management Plan-Update.
3. Drafts of resolution on wild horse and burros and letter regarding Desert Tortoise Conservation Center.
4. Panaca Summit wild horse herd and public safety.
5. Nevada Power on transmission corridor planning.
6. Status of off-road races and problems with desert tortoise.
7. Past history of recreation uses and conflicts with other land uses, along with future plans regarding increased recreational use.
8. Camping restrictions.
9. Update on cattle association appeal regarding grazing restrictions.
10. Public comment.

Advisory Council meetings are open to the public. Persons wishing to make oral statements to the Council must notify the District Manager, Bureau of Land Management, Las Vegas District, P.O. Box 26569, Las Vegas, Nevada 89126, prior to May 8, 1992.

Minutes of the meeting will be available, upon request, at the Las Vegas District Office on May 29, 1992.

Date: April 15, 1992.

Ben F. Collins,

District Manager, Las Vegas, Nevada.

[FR Doc. 92-9789 Filed 4-27-92; 8:45 am]

BILLING CODE 4310-HC-M

[NM-930-02-4212-02]

Redelegation of Authority for Lands Casework, New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Redelegation of authority.

SUMMARY: Pursuant to the authority in Bureau Manual 1203 dated July 17, 1990, the State Director, New Mexico State Office, has redelegated the authority for all lands adjudication functions and responsibilities from NM (940) to NM (930). Authority for processing applications for new withdrawals is also redelegated to the District Managers in New Mexico and Oklahoma.

EFFECTIVE DATE: March 8, 1992.

ADDRESSES: Comments should be sent to the New Mexico State Director, P.O. Box 27115, Santa Fe, New Mexico 87502-7115.

FOR FURTHER INFORMATION CONTACT: Clarence F. Hougland, New Mexico State Office, (505) 438-7593.

SUPPLEMENTARY INFORMATION: Due to a recent reorganization in the New Mexico State Office, all lands adjudication functions and responsibilities in the Division of Operations were redelegated, effective March 8, 1992, to the Division of Lands and Renewable Resources. All land patents, other conveyance documents, and disclaimers, including patents for Conveyances of Mineral Interest, will now be signed by the Deputy State Director for Lands and Renewable Resources. Effective October 1, 1992, the processing of applications for new withdrawals was redelegated to the District Managers in New Mexico and Oklahoma. All applications for new withdrawals, including applications for new withdrawals on Forest Service land will now be filed in the following District Offices:

Albuquerque District Office, 435 Montano NE., Albuquerque, New Mexico 87107, (505) 761-8700

Las Cruces District Office, 1800 Marquess Street, Las Cruces, New Mexico 88005, (505) 525-8228

Roswell District Office, P.O. Box 1397, 1717 W. Second, Roswell, New Mexico 88202-1397, (505) 622-9042

Tulsa District Office, 9522-H E. 47th Place, Tulsa, Oklahoma 74145, (918) 621-4100

Dated: April 16, 1992.

Monte G. Jordan,

Associate State Director.

[FR Doc. 92-9765 Filed 4-27-92; 8:45 am]

BILLING CODE 4310-FB-M

[CA-060-02-4212-13; CA-29832]

Realty Action; Exchange of Public and Private Lands in Riverside and San Diego Counties, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of realty action; exchange of public and private lands, CA-29832.

SUMMARY: The following described public land is being considered for disposal by exchange under section 206 of the Federal Land Policy and Management Act of October 21, 1976 (43 U.S.C. 1716):

San Bernardino Meridian, Riverside County, California

T. 8 S., R. 1 E.,
Sec. 4: Lots 1-4, S½NE¼;
Sec. 5: Lots 3, 4;
Sec. 22: Lots 10-15, Lots 17, 18;
Sec. 27: NW¼, NE¼, N½NW¼, NE¼SW¼, NW¼SE¼.

T. 7 S., R. 2 E.,
Sec. 12: Lots 1-8, SW¼NE¼, S½NW¼, N½SW¼, SE¼SW¼, W½SE¼.

T.7 S., R. 3 E.,
Sec. 18: SW¼SE¼, W½W½SE¼SE¼, E½E½SE¼SE¼.

The total of selected public lands is 1,552.98 acres, more or less

In exchange for these lands, the United States will acquire the following described non-federal lands:

San Bernardino Meridian, Riverside County, California

T. 8 S., R. 3 E.,
Sec. 27;
Sec. 35.

Containing 1,280 acres, more or less.

San Bernardino Meridian, San Diego County, California

T. 8 S., R. 3 E.,
Sec. 36: Lots 1-4, Lots 6-8, Lot 5 Excepting therefrom that portion described as follows:

Beginning at the southwest corner of said section 36; thence northerly along the west line of said section, 1320.00 feet; thence easterly parallel with the south line of said section, 330.00 feet; thence southerly parallel with the west line of said section, 1320.00 feet to a point on the south line of said section 36; thence westerly along said south line 330.00 feet to the point of beginning.

T. 9 S.,R. 3 E.,
Sec. 1: Lots 1-4, S½N½, S½.

Containing 987.03 acres, more or less.

The total of offered private lands is 2,267.03 acres, more or less.

SUPPLEMENTARY INFORMATION: A primary purpose of the exchange is for the Bureau of Land Management (BLM) to acquire the offered private lands and consolidate the public land holdings in the Beauty Mountain Management Area. This is a proposed special recreation and habitat management area. Consolidation of public lands will improve management effectiveness. The acquisition of the offered lands would also tie in with interagency efforts for regional multi-species management by

providing a habitat corridor to link with Anza-Borrego Desert State Park, which will serve to enhance management opportunities.

The values of the lands to be exchanged are approximately equal; full equalization of values will be achieved through acreage adjustment, or by cash payment in an amount not to exceed 25% of the value of the lands being transferred out of federal ownership.

Public lands to be transferred from the United States are subject to the following reservations, terms, and conditions:

1. A reservation to the United States of a right-of-way for ditches or canals constructed by the authority of the United States, under the act of August 30, 1890 (43 U.S.C. 945).
2. Those rights for an existing road (County R3) within Lots 3 and 4, in sec. 5, T. 8 S.,R. 1 E., CA–24794 maintained by the County of Riverside and authorized under R. S. 2477 (43 U.S.C. 932) 1971.
3. Those rights for an existing road (State Highway 371) on an area of public land in Sec. 22 T. 8 S., R. 1 E, CA–29598 maintained by the State of California and authorized under R.S. 2477 (43 U.S.C. 932).

Publication of this notice in the **Federal Register** segregates the public lands from operation of the public land laws and the mining law, except for mineral leasing. The segregative effect will end upon issuance of patent or two years from the date of publication, whichever occurs first.

For detailed information concerning this exchange, contact Russell L. Kaldenberg, Area Manager, Palm Springs-South Coast Resource Area (619) 251–0812.

For a period of 45 days after publication of this Notice in the **Federal Register**, interested parties may submit comments to the District Manager, California Desert District, 6221 Box Springs Boulevard, Riverside, California 92507.

Dated: April 15, 1992.

Jean Rivers-Council,

Associate District Manager.

[FR Doc. 92–9800 Filed 4–27–92; 8:45 am]

BILLING CODE 4310–40–M

[OR–015–4212–14: G–2–205; OR 36857C, OR 48075, OR 48076]

The following parcels of public land are suitable for direct sale under section 203 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1713, at no less than the appraised fair market value. The land will not be offered for sale until at least 60 days after publication of this notice:

Legal description	Acreage	Sale price	Deposit
Parcel No. 1, OR 36857C; T.27S., R.17E., W.M., Oregon, Section 33: SW¼SW¼	40	$2,200.00	$660
Parcel No. 2, OR 48075; T.27S., R.16E., W.M., Oregon, Section 7: E½NW¼	80	4,400.00	1,320.00
Parcel No. 3, OR 48076; T.27S., R.15E., W.M., Oregon, Section 1: Lots 1,2,3, S½NE¼, SE¼NW¼	241.26	13,270.00	2,654.00

The above described land parcels are hereby segregated from appropriation under the public land laws, including the mining laws, but not from sale under the above sited statute for 270 days or until title transfers are completed or the segregation is terminated by publication in the **Federal Register**, whichever occurs first.

This land is difficult and uneconomic to manage as part of the public lands and is not suitable for management by another federal agency. No significant resource values will be affected by this disposal. The sale is consistent with Bureau's planning for the land involved and the public interest will be served by the sale.

The sale parcels OR 36857C, OR 48075 and OR 48076 are being offered to John Pettus of Christmas Valley, Oregon, Herb Vloedman and Gene Porter of Fort Rock, Oregon, respectively, using direct sale procedures authorized under 43 CFR 2711.3–3. Direct sales are appropriate, in these cases, as the designated purchasers are adjoining landowners who use and wish to consolidate the subject properties into their existing business operations.

Any of the designated purchasers wishing to purchase their respective parcel on time, must submit the minimum deposit indicated at the time of sale offering and will be required to tender the remainder of the purchase price within 180 days from said sale date. Failure to submit the remainder of the full sale price within 180 days from the date of sale shall result in sale cancellation and deposit forfeiture.

The terms, conditions and reservations applicable to the sales are as follows:

1. Patents will contain a reservation to the United States for ditches and canals.

2a. All minerals in the lands involving sale parcels OR 36857C and OR 48075 will be reserved to the United States in accordance with section 209 of the Federal Land Policy and Management Act of 1976.

2b. The mineral interests being offered for conveyance in sale parcel OR 48076 have no known value. A deposit or bid to purchase this parcel will also constitute an application for conveyance of the mineral estate, (with the exception of the oil and gas and geothermal resources which will be reserved to the United States) in accordance with section 209 of the Federal Land Policy and Management Act of 1976. The designated purchaser or any future qualified bidder must include with their deposit a non-refundable $50.00 filing fee for conveyance of the mineral estate.

3. The sales will be subject to all valid existing rights of record at the time of sale.

If the land identified in this notice is not sold to the designated purchasers within 90 days of sale offering the unsold parcels will be available for over-the-counter sale until sold or withdrawn from the sale. Sealed bids will be accepted on the unsold parcels at the Lakeview District Office during regular business hours (7:45 a.m. to 4:30 p.m. Monday through Friday) at the address shown below. All sealed bids received will be opened the first Wednesday of each subsequent month until the land is either sold or withdrawn from sale. Prospective buyers should inquire about unsold parcels approximately 150 days from the date this notice is published in the **Federal Register**.

Detailed information concerning the sale, including the reservations, sale procedures, conditions, planning and environmental documentation, is available at the Lakeview District Office, P.O. Box 151, 1000 South Ninth Street, Lakeview, Oregon 97630.

For a period of 45 days from the date of publication of this notice in the **Federal Register**, interested parties may submit comments to the District Manager, Bureau of Land Management, at the above address. Objections will be reviewed by the District Manager who may sustain, vacate or modify this realty action. In the absence of any objections, this realty action will become the final

determination of the Department of the Interior.

April 15, 1992.

Terry H. Sodorff,

Acting District Manager.

[FR Doc. 92-9764 Filed 4-27-92; 8:45 am]

BILLING CODE 4310-33-M

[OR-47431; OR 030-01-4212-13; GP2-175]

Realty Action; Exchange of Public Lands; Wallowa County, Oregon

The following described public lands are determined to be suitable for disposal by exchange under Section 6 of the Wild and Scenic rivers Act of 1968, 16 U.S.C. 1277, and section 206 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1716.

Willamette Meridian, Oregon

T. 6 N., R. 46 E., WM.,
Sec. 14, Lots 1-4;
Sec. 15, Lots 1;
Sec. 24, Lots 1-5, N½SW¼, W½SE¼, SE¼SE¼;
Sec. 25, E½E½.
T. 2 N., R. 47 E., WM.,
Sec. 10, SE¼SE¼;
Sec. 13, NE¼NE¼.
T. 6 N., R. 47 E., WM.,
Sec. 30, W½W½.

The area described aggregates 954.97 acres in Wallowa County, Oregon.

In exchange for these lands, the United States will acquire the following described private lands from Clearwater Realty Company.

Willamette Meridian, Oregon

T. 6 N., R. 43 E., WM.,
Sec. 23, S½NE¼;
Sec. 24, SW¼NW¼;
Sec. 34, SE¼NE¼, NE¼SE¼, N½SE¼SE¼, SW¼SE¼SE¼, and that part of the SW¼NE¼, W½SE¼, and SE¼SW¼ lying South and East of the Grande Ronde River;
Sec. 35, N½NW¼NW¼SW¼, and SW¼NW¼NW¼SW¼.
T. 5 N., R. 43 E.,WM.,
Sec. 3, SE¼NW¼, NE¼SW¼, N½NW¼NE¼NE¼, NW¼NE¼NW¼NE¼, N½NW¼NW¼NE¼, SW¼NW¼NW¼NE¼, and that part of the SW¼NW¼, and NE¼NW¼ lying South and East of the Grande Ronde River.

The area described aggregates 477.00 acres in Wallowa County, Oregon.

The purpose of this land exchange is to acquire non-federal lands within the Grande Ronde Wild and Scenic River corridor and the Grande Ronde ACEC. The exchange would create a more logical and efficient land management pattern and will help provide protection and management of recreation, riparian and aesthetic values within the above described special management areas. The exchange is being pursued with the view that disposal of isolated public lands and the acquisition of offered private lands within special management areas will serve the public interest. The exchange is consistent with the Bureau's planning for the lands involved.

The value of the lands to be exchanged is approximately equal. The acreages will be adjusted to equalize the values following completion of the final appraisal.

The exchange will be subject to:

1. The reservation to the United States of a right-of-way for ditches and canals constructed by the authority of the United States, Act of August 30, 1890 (43 U.S.C. 945).

2. All valid existing rights, including but not limited to any right-of-way, easement or lease of record. The existing rights of record are as follows: County Road No. 699.

3. Mineral rights may be reserved, depending upon the findings in the mineral report.

All necessary reports and clearances, including the environmental analysis, cultural resources, and threatened and endangered plants and animals, shall be completed prior to conveyance of title. When completed, these documents and other information concerning the exchange will be available for review at the Baker Resource Area Office, 1550 Dewey Avenue, Baker City, Oregon 97814 or the Value District Office, 100 Oregon Street, Vale, Oregon 97918.

The publication of this notice in the **Federal Register** will segregate the public lands described above from appropriation under the public land laws, including the mining laws, except from exchange pursuant to section 6 of the Wild and Scenic River Act of 1968 and section 206 of the Federal Land Policy and Management Act of 1976. As provided by the regulations of 43 CFR 2201.1(b), any subsequently tendered application, allowance of which is discretionary, shall not be accepted, shall not be considered as filed, and shall be returned to the applicant. The segregative effect of this notice will terminate upon issuance of patent or in two year, whichever comes first.

For additional information concerning this exchange, contact Jim Ledger, BLM Baker Resource Area Office, (503) 523-6391, Ext. 324.

For a period of 45 days from the date of publication of this notice in the **Federal Register** interested parties may submit comments to the District Manager, Vale District, 100 East Oregon Street, Vale, Oregon 97918. Objections will be reviewed by the State Director who may sustain, vacate, or modify this realty action. In the absence of any objection, this realty action will become the final determination of the Department of the Interior.

Dated: April 13, 1992.

James E. May,

District Manager.

[FR Doc. 92-9761 Filed 4-27-92; 8:45 am]

BILLING CODE 4310-33-M

[WY-030-4212-14; WYW 123061]

Realty Action; Direct Sale of Public Lands; WY

AGENCY: Bureau of Land Management, Interior.

ACTION: Correction of notice of realty Action; Sale of public lands in Carbon County.

SUMMARY: On October 11, 1991, a notice of realty action was published in the **Federal Register** (55 FR 51400) that determined the following described lands were suitable for direct sale under sections 203 and 209 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1713, 1719 (1988):

Sixth Principal Meridian

T. 18 N., R. 84 W.,
Sec. 26, S½S½SW¼NE¼SW¼.

The above land contains 2.5 acres.

FOR FURTHER INFORMATION CONTACT: Jennene Nelson, Supervisory Realty Specialist, Great Divide Resource Area, Bureau of Land Management, 812 East Murray Street, P.O. Box 670, Rawlins, Wyoming 82301, 307-324-4841.

SUPPLEMENTARY INFORMATION: The Bureau of Land Management proposes to sell the above lands, surface and mineral estates, except coal, to the Bell Ranch, pursuant to sections 203 and 209 of the Federal Land Policy and Management Act of 1976. The mineral interests being offered have no known mineral value. The proposed direct sale will be made at fair market value. Bell Ranch will be required to submit a non-refundable application fee of $50.00 in accordance with section 209(b) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1719(b).

Conveyance of the above public land will be subject to:

1. Reservation of a right-of-way for ditches or canals pursuant to the Act of August 30, 1890, 43 U.S.C. 945;
2. Reservation of coal;
3. Oil and gas lease BLM Serial Number WYW 86440 granted to Carbon Power and Light, Inc.

A more detailed description of the reservations, which will be incorporated into the patent document, is available

for review at the BLM, Great Divide Resource Area Office.

Dated: April 17, 1992.

Alan R. Pierson,

District Manager.

[FR Doc. 92-9763 Filed 4-27-92; 8:45 am]

BILLING CODE 4310-22-M

Fish and Wildlife Service

Garrison Diversion Unit Federal Advisory Council Meeting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of meeting.

SUMMARY: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. I), this notice announces a meeting of the Garrison Diversion Unit Federal Advisory Council (Council) established under the authority of the Garrison Diversion Unit Reformulation Act of 1986 (Pub. L. 99-294, May 12, 1986). The meeting is open to the public. Interested persons may make oral statements to the Council or may file written statements for consideration.

DATES: The Garrison Diversion Unit Federal Advisory Council will meet from 8 a.m. to 4 p.m. on Tuesday, May 12, 1992.

ADDRESSES: The meeting will be held at the North Dakota Game and Fish Department, 100 North Bismarck Expressway, Bismarck, North Dakota.

SUPPLEMENTARY INFORMATION: The Council will consider and discuss subjects such as the Lonetree Area tax issue, Wetlands Trust, Kraft Slough Acquisition update, National Wildlife Refuge Compatibility requirements, Preliminary Draft Comprehensive Mitigation Plan for Audubon National Wildlife Refuge, Audubon Lake mitigation implementation, progress and future schedule, Proposed Comprehensive Mitigation Plan for the Audubon Wildlife Management Area, comparative costs of various duck production techniques, recommendations to meet compatibility requirements at Audubon National Wildlife Refuge and Wildlife Management Area, and history of Garrison Diversion Unit impacts on Arrowwood National Wildlife Refuge and mitigation and compatibility progress.

On Wednesday, May 13, 1992, the Council will visit Arrowwood National Wildlife Refuge to review mitigation work that is in progress.

For further information, contact Dr. Grady Towns, Fish and Wildlife Enhancement, at (303) 236-8186.

Dated: April 15, 1992.

Galen L. Buterbaugh,

Regional Director, Region 6.

[FR Doc. 92-9799 Filed 4-27-92; 8:45 am]

BILLING CODE 4310-55-M

Minerals Management Service

Outer Continental Shelf Oil and Gas Lease Sales; List of Restricted Joint Bidders

Pursuant to the authority vested in the Director of the Minerals Management Service by the joint bidding provisions of 30 CFR 256.41, each entity within one of the following groups shall be restricted from bidding with any entity in any other of the following groups at Outer Continental Shelf oil and gas lease sales to be held during the bidding period from May 1 through October 31, 1992. The List of Restricted Joint Bidders published in the **Federal Register** on October 30, 1991, at 56 FR 55928 covered the bidding period of November 1, 1991, through April 30, 1992.

Group I.
- Chevron Corporation; Chevron U.S.A. Inc.

Group II.
- Exxon Corp.; Exxon San Joaquin Production Co.

Group III.
- Shell Oil Co.; Shell Offshore Inc.; Shell Western E&P Inc.

Group IV.
- Mobil Oil Corp.; Mobil Oil Exploration and Producing Southeast Inc.; Mobil Producing Texas and New Mexico Inc.; Mobil Exploration and Producing North America Inc.

Group V.
- BP America Inc.; The Standard Oil Co.; BP Exploration & Oil Inc.; BP Exploration (Alaska) Inc.

Dated: April 22, 1992.

Scott Sewell,

Director, Minerals Management Service.

[FR Doc. 92-9940 Filed 4-27-92; 8:45 am]

BILLING CODE 4310-MR-M

National Park Service

National Register of Historic Places; Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before April 17, 1992. Pursuant to § 60.13 of 36 CFR part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, P.O. Box 37127, Washington, DC 20013-7127. Written comments should be submitted by May 13, 1992.

Carol D. Shull,

Chief of Registration, National Register.

Arkansas

Conway County

Administration Office (Facilities Constructed by the CCC in Arkansas MPS), AR 154 E of Bench Mark 914, Petit Jean State Park, Winrock vicinity, 92000520

Blue Hole Road District (Facilities Constructed by the CCC in Arkansas MPS), Blue Hole Rd., Petit Jean State Park, Winrock vicinity, 92000513

Cabin No. 1 (Facilities Constructed by the CCC in Arkansas MPS), Campground access rd., Petit Jean State Park, Winrock vicinity, 92000523

Cabin No. 16 (Facilities Constructed by the CCC in Arkansas MPS), Campground access rd., Petit Jean State Park, Winrock vicinity, 92000522

Cabin No. 6 (Facilities Constructed by the CCC in Arkansas MPS), Campground access rd., Petit Jean State Park, Winrock vicinity, 92000524

Cabin No. 9 (Facilities Constructed by the CCC in Arkansas MPS), Campground access rd., Petit Jean State Park, Winrock vicinity, 92000525

Cedar Falls Trail Historic District (Facilities Constructed by the CCC in Arkansas MPS), Adjacent to main access rd., Petit Jean State Park, Winrock vicinity, 92000514

Concrete Log Bridge (Facilities Constructed by the CCC in Arkansas MPS), AR 154 S of Bench Mark 914, Petit Jean State Park, Winrock vicinity, 92000519

Culvert No. 1 (Facilities Constructed by the CCC in Arkansas MPS), AR 154, Petit Jean State Park, Winrock vicinity, 92000518

Lake Bailey—Roosevelt Lake Historic District (Facilities Constructed by the CCC in Arkansas MPS), E and N of AR 154, Petit Jean State Park, Winrock vicinity, 92000515

Mather Lodge (Facilities Constructed by the CCC in Arkansas MPS), Main access rd., Petit Jean State Park, Winrock vicinity, 92000521

Office Headquarters (Facilities Constructed by the CCC in Arkansas MPS), AR 154, approximately 500 ft. S of Bench Mark 914, Petit Jean State Park, Winrock vicinity, 92000516

Water Treatment Building (Facilities Constructed by the CCC in Arkansas MPS), On dirt access rd. S of jct. with AR 154, approximately 800 ft. E of Bench Mark 914, Petit Jean State Park, Winrock vicinity, 92000517

Greene County

Amphitheater (Facilities Constructed by the CCC in Arkansas MPS), Main service center area access rd., Crowley's Ridge State Park, Walcott vicinity, 92000541

Bathhouse (Facilities Constructed by the CCC in Arkansas MPS), Main service center area access rd., Crowley's Ridge State Park, Walcott vicinity, 92000537

Bridge (Facilities Constructed by the CCC in Arkansas MPS), Main service center area

access rd., Crowley's Ridge State Park, Walcott vicinity, 92000540

Comfort Station (Facilities Constructed by the CCC in Arkansas MPS), Campground and cabin area access rd., Crowley's Ridge State Park, Walcott vicinity, 92000538

Culvert No. 1 (Facilities Constructed by the CCC in Arkansas MPS), Hiking area access rd., Crowley's Ridge State Park, Walcott vicinity, 92000539

Dining Hall (Facilities Constructed by the CCC in Arkansas MPS), Employee housing area access rd., Crowley's Ridge State Park, Walcott vicinity, 92000536

Hot Spring County

Bridge No. 2 (Facilities Constructed by the CCC in Arkansas MPS), AR 171 W of Slunger Cr., Lake Catherine State Park, Shorewood Hills vicinity, 92000528

Cabin No. 2 (Facilities Constructed by the CCC in Arkansas MPS), Cabin area access rd., Lake Catherine State Park, Shorewood Hills vicinity, 92000526

Cabin No. 3 (Facilities Constructed by the CCC in Arkansas MPS), Cabin area access rd., Lake Catherine State Park, Shorewood Hills vicinity, 92000527

Culvert No. 4 (Facilities Constructed by the CCC in Arkansas MPS), AR 171 S of Slunger Bay, Lake Catherine State Park, Shorewood Hills vicinity, 92000529

Nature Cabin (Facilities Constructed by the CCC in Arkansas MPS), Camping area access rd., Lake Catherine State Park, Shorewood Hills vicinity, 92000535

Retaining Wall No. 1 (Facilities Constructed by the CCC in Arkansas MPS), Employee housing area access rd., Lake Catherine State Park, Shorewood Hills vicinity, 92000530

Retaining Wall No. 2 (Facilities Constructed by the CCC in Arkansas MPS), Visitor center access rd., Lake Catherine State Park, Shorewood Hills vicinity, 92000531

Retaining Wall No. 3 (Facilities Constructed by the CCC in Arkansas MPS), Campground access rd., Lake Catherine State Park, Shorewood Hills vicinity, 92000532

Retaining Wall No. 4 (Facilities Constructed by the CCC in Arkansas MPS), On S shore of Slunger Bay, N of visitor center access rd., Lake Catherine State Park, Shorewood Hills vicinity, 92000533

Retaining Wall No. 5 (Facilities Constructed by the CCC in Arkansas MPS), Secondary campground access rd., Lake Catherine State Park, Shorewood Hills vicinity, 92000534

Yell County

Directional Stones (Facilities Constructed by the CCC in Arkansas MPS), On Darling Springs Trail, approximately 600 ft. SW of AR 151, Mount Nebo State Park, Dardanelle vicinity, 92000547

Gum Springs (Facilities Constructed by the CCC in Arkansas MPS), 2600 ft. SW of AR 151, Mount Nebo State Park, Dardanelle vicinity, 92000545

Nebo Springs (Facilities Constructed by the CCC in Arkansas MPS), 1150 ft. N of AR 151, Mount Nebo State Park, Dardanelle vicinity, 92000544

Nebo Springs Trail (Facilities Constructed by the CCC in Arkansas MPS), On Rim Trail, approximately 2250 ft. SW of AR 151, Mount Nebo State Park, Dardanelle vicinity, 92000548

Nebo Steps Trail (Facilities Constructed by the CCC in Arkansas MPS), NE of visitors center, Mount Nebo State Park, Dardanelle vicinity, 92000549

Pavilion (Facilities Constructed by the CCC in Arkansas MPS), N of AR 155, Mount Nebo State Park, Dardanelle vicinity, 92000542

Retaining Wall (Facilities Constructed by the CCC in Arkansas MPS), 400 ft. W of AR 151, Mount Nebo State Park, Dardanelle vicinity, 92000543

Steps No. 5 (Facilities Constructed by the CCC in Arkansas MPS), 2400 ft. SW of AR 151, Mount Nebo State Park, Dardanelle vicinity, 92000546

COLORADO

Larimer County

Arrowhead Lodge 34500 Poudre Canyon Hwy., Roosevelt NF, Bellvue, 92000502

FLORIDA

Brevard County

Community Chapel of Melbourne Beach, 501 Ocean Ave., Melbourne Beach, 92000505

LOUISIANA

Livingston Parish

Decareaux House (Louisiana's French Creole Architecture MPS), 16021 LA 16, French Settlement, 92000507

Guitreau House (Louisiana's French Creole Architecture MPS), 16825 LA 16, French Settlement, 9200058

Lobell, Adam, House (Louisiana's French Creole Architecture MPS), 15715 LA 16, French Settlement, 92000509

Pointe Coupee Parish

Bergeron, Valmont, House (Louisiana's French Creole Architecture MPS), LA 414, Jarreau vicinity, 92000512

St. James Parish

Graugnard Farms Plantation House (Louisiana's French Creole Architecture MPS), 5825 LA 18, St. James vicinity, 92000510

Little Texas (Louisiana's French Creole Architecture MPS), 2834 LA 44, Paulina vicinity, 92000511

MISSOURI

Cole County

Jefferson City Community Center, 608 E. Dunklin St., Jefferson City, 92000503

St. Charles County

Staudinger—Grumke House—Store, 5503 Locust St., Augusta, 92000504

NEW MEXICO

Los Alamos County

White Rock Canyon (Boundary Increase), Address Restricted, White Rock vicinity, 92000501

TENNESSEE

Knox County

Old North Knoxville Historic District, Roughly bounded by E. Woodland, Bluff, Armstrong, E. Baxter and Central Aves., Knoxville, 92000506

[FR Doc. 92-9654 Filed 4-27-92; 8:45 am]

BILLING CODE 4310-70-M

Bureau of Land Management

[CA-065-02-4352-12]

Temporary Closure of Vehicle Route and Temporary Camping Restrictions in the Eureka Valley Dunes Area of Critical Environmental Concern, Inyo County, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of temporary closure and camping restrictions in the Eureka Valley Dunes Area of critical environmental concern, Inyo County, CA.

SUMMARY: Notice is hereby given that one route is closed to vehicle use and camping is restricted to designated sites and parking areas within the Eureka Valley Dunes Area of Critical Environmental Concern.

ORDER: Effective immediately, the vehicle route that runs approximately ⅓ the length of the west side of the Eureka Dunes is closed to all vehicle use. No person may use, drive, transport, park, let stand or have charge or control over any vehicle on this route. Camping is restricted to designated sites and established parking areas. Camping is prohibited on the Dunes and within ⅛ mile of the Dunes.

Exemptions to this order are granted to law enforcement and other emergency vehicles in the course of official duties. All other exemptions to this order are by written authorization of the Ridgecrest Resource Area Manager only.

EFFECTIVE DATE: This closure is effective immediately and will remain in effect until June 12, 1992.

FOR FURTHER INFORMATION CONTACT: Area Manager, 300 South Richmond Road, Ridgecrest, CA 93555, 619-375-7125.

SUPPLEMENTARY INFORMATION: The purpose of the Temporary Closure and Restriction Order is to provide increased protection to the federally listed endangered species, Eureka Dunes Evening Primrose *Oenothera avita* ssp. *eurekensis*;).

Maps showing the route and areas affected by this Order are available by contacting the Ridgecrest Resource Area Office. The affected route will be posted with the standard vehicle "Closed Area" sign. Designated camping sites will be

posted with the standard camping symbol signs. Areas where camping is prohibited will be posted with the standard camping symbol with red slash signs.

Authority for this temporary closure and camping restriction is found in 43 CFR 8364.1. Violation of this Order is punishable by a fine not to exceed $100,000 and/or imprisonment not to exceed 12 months.

Dated: April 16, 1992.

Alan Stein,

Acting District Manager.

[FR Doc. 92-9762 Filed 4-27-92; 8:45 am]

BILLING CODE 4310-40-M

INTERNATIONAL DEVELOPMENT COOPERATION AGENCY

Agency for International Development

Renewal of the International Disaster Advisory Committee

AGENCY: Agency for International Development (A.I.D.).

ACTION: Renewal of advisory committee.

SUMMARY: The Administrator of A.I.D. has determined that it is in the public interest to renew the International Disaster Advisory Committee. The Committee advises A.I.D. on means to increase participation by the U.S. private sector in all aspects of international disaster assistance, including risk reduction, disaster preparedness, and disaster response.

FOR FURTHER INFORMATION CONTACT: Mr. Oliver Davidson, OFDA/IDAC, room 1262A New State, Agency for International Development, Washington, DC 20523—(202) 647-5210.

Jan Miller,

Assistant General Counsel for Employee and Public Affairs.

[FR Doc. 92-9770 Filed 4-27-92; 8:45 am]

BILLING CODE 6116-01-M

INTERSTATE COMMERCE COMMISSION

[Ex Parte No. 506]

Railroad Cost of Capital—1991

AGENCY: Interstate Commerce Commission.

ACTION: Notice of decision.

SUMMARY: On April 27, 1992, the Commission served a decision to update its estimate of the railroad industry's cost of capital for 1991. The composite cost of capital rate for 1991 is found to be 11.6 percent, based on a current cost of debt of 8.8 percent, a cost of preferred equity capital of 5.1 percent, a cost of common equity capital of 12.9 percent, and a 30.2 percent debt/1.3 percent preferred equity/68.5 percent common equity capital structure mix. The cost of capital finding made in this proceeding will enable the Commission to make its annual determination of railroad revenue adequacy for 1991.

EFFECTIVE DATE: April 27, 1992.

FOR FURTHER INFORMATION CONTACT: Ward L. Ginn, Jr. (202) 927-6187, (TDD for hearing impaired: (202) 927-5721).

SUPPLEMENTARY INFORMATION: The cost of capital finding in this decision should be used to evaluate the adequacy of railroad revenues for 1991 under the standards and procedures promulgated in *Standards for Railroad Revenue Adequacy*, 3 ICC2d 261 (1986). This finding may also be used in proceedings involving the prescription of maximum reasonable rate levels.

Additional information is contained in the Commission's decision. To purchase a copy of the full decision, write to, call, or pick up on person from: Dynamic Concepts, Inc., Room 2229, Interstate Commerce Commission Building, Washington, DC 20423. Telephone (202) 289-4357. (Assistance for the hearing impaired is available through TDD services (202) 927-5721).

Decided: April 17, 1992.

By the Commission, Chairman Philbin, Vice Chairman McDonald, Commissioners Simmons, Phillips, and Emmett.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 92-9876 Filed 4-27-92; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF JUSTICE

Lodging of Final Judgment by Consent Pursuant to the Safe Drinking Water Act

In accordance with Departmental policy, 28 CFR 50.7, notice is hereby given that on April 24, 1992, a consent decree in *United States of America and the State of Montana* v. *Silver Bow Water, Inc. and the City-County of Butte-Silver Bow, Montana*, No. CV-92-26-BU-PGH, was lodged in the United States District Court for the District of Montana.

The complaint, filed simultaneously with the consent decree, alleges that SBWI and the City-County, the new owner and operator of the Butte, Montana water system, committed violations of the Safe Drinking Water Act ("SDWA") and the national primary drinking water regulations and will continue to do so unless enjoined, and that under section 1414(b) of the SDWA, 42 U.S.C. 300g-3(2), the defendants are liable for civil penalties of up to $25,000 per day of violation and injunctive relief. The complaint also alleges that there is an imminent and substantial endangerment, within the meaning of section 1431 of the SDWA, 42 U.S.C. 300i, to persons who consume drinking water from the Butte water system. The State, which has primary responsibility for enforcing the national primary drinking water regulations in Montana, also signed the complaint and alleged violations of the Montana Public Water Supply Act (MPWSA), Mont. Code Ann. tit. 75, ch. 6, pt. 1 (the State analogue to the SDWA), and the regulations promulgated thereunder, Mont. Admin. R. section 16.20.205. In addition, the State alleged that under Mont. Code Ann. section 75-6-111(2), the defendants are liable for civil penalties of up to $10,000 per day of violation and for injunctive relief.

The consent decree, signed by the Environmental Protection Agency, the State, SBWI, and the City-County, resolves the United States' claims against SBWI and the City-County (the "Settlors") under Sections 1414 and 1431 of the SDWA, 42 U.S.C. 300g-3 and 300i. Under the proposed Decree, the Settlors are required, *inter alia*, to construct two drinking water filtration facilities on an expedited schedule and mitigate turbidity in the Butte water system until the filtration plants are completed. The decree provides all of the injunctive relief sought by the United States from the Settlors, as well as stipulated penalties for violations of the SDWA and the decree. In addition, the decree provides a covenant not to sue for statutory penalties for violations of the turbidity and microbiological contaminants MCL's during the construction period, conditioned upon the Settlors achieving complete compliance with the SDWA and the national primary drinking water regulations by December 31, 1994. The decree will not terminate until the Settlors have established, *inter alia*, complete compliance with the SDWA for a period of 12 months. The decree does not affect the United States' claims for civil penalties pending in *United States* v. *Butte Water Company*, No. CV-91-100-BU-PGH (D. Mont.).

The Department of Justice will receive comments relating to the proposed consent decree for a period of fourteen days from the date of publication of this notice. Comments should be addressed to the Acting Assistant Attorney General, Environment and Natural

Resources Division, Department of Justice, Washington, DC 20530, and should refer to *United States* v. *Silver Bow Water, Inc.*, DOJ Ref. No. 90-5-1-1-3751A. The proposed consent decree may be examined at the office of the United States Attorney, District of Montana, 167 Federal Building, Butte, Montana. Copies of the decree may also be examined and obtained by mail at the Environmental Enforcement Section Document Center, 601 Pennsylvania Avenue, NW., Box 1097, Washington, DC 20004 (202-347-7829). When requesting a copy of the consent decree by mail, please enclose a check in the amount of $12.50 (twenty-five cents per page reproduction costs) payable to the "Consent Decree Library."

Barry M. Hartman,

Acting Assistant Attorney General, Environment and Natural Resources Division.

[FR Doc. 92-10047 Filed 4-27-92; 9:46 am]

BILLING CODE 4410-01-M

Drug Enforcement Administration

Manufacturer of Controlled Substances: Notice of Registration

By Notice dated December 30, 1991, and published in the **Federal Register** on January 16, 1992 (57 FR 1929), Hoffman-La Roche Inc., 340 Kingsland Street, Nutley, New Jersey 07110, made application to the Drug Enforcement Administration to be registered as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Tetrahydrocannabinols (7370)	I
Levorphanol (9220)	II

No comments or objections have been received. Therefore, pursuant to section 303 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and title 21, Code of Federal Regulations, section 1301.54(e), the Deputy Assistant Administrator hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic classes of controlled substances listed above is granted.

Dated: April 21, 1992.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

FR Doc. 92-9769 Filed 4-27-92; 8:45 am]

BILLING CODE 4410-09-M

Manufacturer of Controlled Substances; Notice of Registration

By notice dated December 30, 1991, and published in the **Federal Register** on January 14, 1992 (57 FR 1495), Norac Company, Inc., 405 A. Motor Avenue, Azusa, California 91702, made application to the Drug Enforcement Administration to be registered as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Ibogaine (7260)	I
Tetrahydrocannabinols (7370)	I

No comments or objections have been received. Therefore, pursuant to section 303 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and title 21, Code of Federal Regulations, § 1301.54(e), the Deputy Assistant Administrator hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of a basic class of controlled substance listed above is granted.

Dated: April 21, 1992.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 92-9767 Filed 4-27-92; 8:45 am]

BILLING CODE 4410-09-M

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated December 30, 1991, and published in the **Federal Register** on January 14, 1992 (57 FR 1495), Toxi-Lab, Inc., 2 Goodyear, Irvine, California 92718, made application to the Drug Enforcement Administration to be registered as a bulk manufacturer of the basic class of controlled substances listed below:

Drug	Schedule
Phencyclidine (7471)	II
1-Piperidinocyclohexanecarbonitrile (8603).	II
Benzoylecgonine (9180)	II

No comments or objections have been received. Therefore, pursuant to section 303 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and title 21, Code of Federal Regulations, section 1301.54(e), the Deputy Assistant Administrator hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic class of controlled substances listed above is granted.

Dated: April 21, 1992.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 92-9768 Filed 4-27-92; 8:45 am]

BILLING CODE 4410-09-M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 92-25]

NASA Advisory Council (NAC), Space Science and Applications Advisory Committee (SSAAC), Astrophysics Subcommittee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92-463, as amended, the National Aeronautics and Space Administration announces a forthcoming meeting of the NASA Advisory Council, Space Science and Applications Advisory Committee, Astrophysics Subcommittee.

DATES: May 21, 1992, 9 a.m. to 4:15 p.m.

ADDRESSES: The National Aeronautics and Space Administration, 600 Independence Avenue SW., room 226, Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Ms. Lia LaPiana, Code SZ, National Aeronautics and Space Administration, Washington, DC 20546 (202/453-1433).

SUPPLEMENTARY INFORMATION: The Space Science and Applications Advisory Committee (SSAAC) consults with and advises the NASA Office of Space Science and Applications (OSSA) on long-range plans for, work in progress on, and accomplishments of NASA's Space Science and Applications programs. The Astrophysics Subcommittee provides advice to the Astrophysics Division and to the SSAAC on operation of the Astrophysics Program and on the formulation and implementation of the Astrophysics research strategy. The Subcommittee will meet to discuss the developments since the January 1992 Astrophysics meeting, Fiscal Year 1993 budget, Advanced X-Ray Astrophysics Facility (AXAF) Restructuring, Space Infrared Telescope Facility (SIRTF), Mission Operations and Data Analysis (MO&DA), Small Explorer Program, Stratospheric Observatory for Infrared Astronomy (SOFIA) and Laser Geodynamics Satellite (LAGEOS) III Missions, and new meeting planning. The Subcommittee is chaired by Dr.

Irwin Shapiro and is composed of 28 members. The meeting will be open to the public up to the capacity of the room (approximately 50 people including Subcommittee members). It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

Type of Meeting: Open.

Agenda:

Thursday, May 21

9 a.m.—Introduction, Developments Since January 1992 Meeting, and the Status of the Fiscal Year 1993 Budget.
10:45 a.m.—AXAF Restructuring.
11:30 a.m.—SIRTF Status.
1 p.m.—MO&DA Productivity Initiative.
2 p.m.—Lessons Learned from the Small Explorer Program.
3:15 p.m.—Update on SOFIA and LAGEOS III Missions.
3:45 p.m.—Astrophysics Subcommittee Membership.
4 p.m.—Future Meeting Planning.
4:15 p.m.—Adjourn.

Dated: April 22, 1992.

Philip D. Waller,

Deputy Director, Management Operations Division.

[FR Doc. 92-9814 Filed 4-27-92; 8:45 am]

BILLING CODE 7510-01-M

NATIONAL COMMISSION ON SEVERELY DISTRESSED PUBLIC HOUSING

Roundtables

AGENCY: National Commission on Severely Distressed Public Housing.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92-463, as amended, the National Commission on Severely Distressed Public Housing announces a forthcoming meeting of the Commission.

DATES: May 1 & 2, 1992.

ADDRESS: Sheridan Woodley, 2600 Woodley Road, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Carmelita Pratt, Administrative Officer, The National Commission on Severely Distressed Public Housing, 1111 18th Street NW., suite 806, Washington, DC 20036 (202) 275-6933.

TYPE OF MEETING: Open.

Due to scheduling difficulties, this notice could not be published 15 days prior to this meeting as required by Federal Advisory Committee Act.

Carmelita R. Pratt,

Administrative Officer.

[FR Doc. 92-9773 Filed 4-27-92; 8:45 am]

BILLING CODE 6820-07-M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Agency Information Collection Activities Under OMB Review

AGENCY: National Endowment for the Arts.

ACTION: Notice.

SUMMARY: The National Endowment for the Arts (NEA) has sent to the Office of Management and Budget (OMB) a request for clearance of the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

DATES: Comments on this information collection must be submitted by May 28, 1992.

ADDRESSES: Send comments to Mr. Dan Chenok, Office of Management and Budget, New Executive Office Building, 726 Jackson Place NW., room 3002, Washington, DC 20503; (202-395-7316). In addition, copies of such comments may be sent to Ms. Judith E. O'Brien, National Endowment for the Arts, Administrative Services Division, room 203, 1100 Pennsylvania Avenue NW., Washington, DC 20506; (202-682-5401).

FOR FURTHER INFORMATION CONTACT: Ms. Judith E. O'Brien, National Endowment for the Arts, Administrative Services Division, room 203, 1100 Pennsylvania Avenue NW., Washington, DC 20506; (202-682-5401).

SUPPLEMENTARY INFORMATION: The Endowment requests the review of a revision of a currently approved collection of information. This entry is issued by the Endowment and contains the following information:

(1) The title of the form; (2) how often the required information must be reported; (3) who will be required or asked to report; (4) what the form will be used for; (5) an estimate of the number of responses; (6) the average burden hours per response; (7) an estimate of the total number of hours needed to prepare the form. This entry is not subject to 44 U.S.C. 3504(h).

Title: FY 93 Locals Program Support to Local Arts Agencies Serving Underserved Areas and Communities.

Frequency of Collection: One Time.

Respondents: State or local governments.

Use: Guideline instructions and applications elicit relevant information from local arts agencies that apply for funding under specific Locals Program categories. This information is necessary for the accurate, fair and thorough consideration of competing proposals in the peer review process.

Estimated Number of Respondents: 40.

Average Burden Hours per Response: 20.

Total Estimated Burden: 800.

Judith E. O'Brien,

Management Analyst, Administrative Services Division, National Endowment for the Arts.

[FR Doc. 92-9867 Filed 4-27-92; 8:45 am]

BILLING CODE 7537-01-M

NUCLEAR REGULATORY COMMISSION

Documents Containing Reporting or Recordkeeping Requirements; Office of Management and Budget (OMB) Review

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of the OMB review of information collection.

SUMMARY: The NRC has recently submitted to OMB for review the following proposal for collection of information under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35).

1. *Type of submission, new, revision, or extension:* Revision.

2. *The title of the information collection:* 10 CFR part 26, Fitness-for-Duty Requirements for Licensees Who Possess, Use, or Transport Category I Material.

3. *The form number if applicable:* Not applicable.

4. *How often the collection is required:* On occasion.

5. *Who will be required or asked to report:* Licensees authorized to possess, use, or transport Category I Material (formula quantities of strategic special nuclear material).

6. *An estimate of the number of reports annually:* 8 (4 semi-annual reports and 4 telephonic event reports). An estimated 600 written statements from individuals requesting unescorted access authorization to strategic special nuclear material are expected.

7. *An estimate of the total number of hours annually needed to complete the requirement or request:* 1,240. 232 hours of reporting burden is estimated (an average 29 hours per response) and 1,008 hours of recordkeeping burden is estimated.

8. *An indication of whether section 3504(h), Public Law 96-511 applies:* Applicable.

9. *Abstract:* The proposed amendments to 10 CFR part 26 of NRC's regulations, "Fitness-for-Duty Programs", would require licensees

authorized to possess, use, or transport Category I Material to implement fitness-for-duty programs to assure that personnel are not under the influence of any substance or mentally or physically impaired, to retain certain records associated with the management of these programs, and to provide reports concerning significant events. The existing requirements for fitness-for-duty programs contained in 10 CFR part 26 are applicable to nuclear power plant personnel and do not include the employees of Category I Material Licensees.

Copies of the submittal may be inspected or obtained for a fee from the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

Comments and questions should be directed to the OMB reviewer: Ronald Minsk, Office of Information and Regulatory Affairs (3150–0146), NEOB–3019, Office of Management and Budget, Washington, DC 20503.

Comments can also be submitted by telephone at (202) 395–3084.

The NRC Clearance Officer is Brenda Jo. Shelton, (301) 492–8132.

Dated at Bethesda, Maryland, this 17th day of April 1992.

For the Nuclear Regulatory Commission.

Gerald F. Cranford,

Designated Senior Official for Information Resources Management.

[FR Doc. 92–9829 Filed 4–27–92; 8:45 am]

BILLING CODE 7590-01-M

Power Authority of the State of New York

[Docket No. 50–286]

Issuance of Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of exemptions from the provisions of: (1) 10 CFR 50.46, which requires the calculation of emergency core cooling system (ECCS) performance for reactors with Zircaloy clad fuel; (2) 10 CFR 50.44, which gives requirements to control the hydrogen generated by Zircaloy clad fuel after a postulated loss-of-coolant-accident (LOCA); and (3) Appendix K to 10 CFR Part 50, which presumes the use of Zircaloy fuel when doing calculations for energy release, cladding oxidation and hydrogen generation after a postulated LOCA. The exemptions would be applicable to Facility Operating License No. DPR–64 and would be issued to the Power Authority of the State of New York, the licensee for Indian Point Nuclear Generating Unit No. 3, located in Westchester county, New York.

Environmental Assessment

Identification of Proposed Action

The proposed action would allow the licensee to use ZIRLO clad fuel in the reactor; ZIRLO's composition falls outside the definition of Zircaloy in the cited regulations. ZIRLO clad fuel assemblies would be loaded into the Indian Point Nuclear Generating Unit No. 3 reactor during the Cycle 8/9 refueling outage in June 1992.

By letter dated January 8, 1992, as supplemented February 26, 1992, the licensee applied for a Technical Specifications amendment and requested exemptions from the Code of Federal Regulations' requirements to allow the use of other than Zircaloy clad fuel.

The Need for the Proposed Action

The exemptions under consideration are needed because 10 CFR 50.46(a)(1)(i) and Appendix K to 10 CFR Part 50 require the demonstration of adequate ECCS performance for light-water reactors that contain fuel consisting of uranium oxide pellets enclosed in Zircaloy tubes; furthermore, 10 CFR 50.44(a) addresses requirements to control hydrogen generated by Zircaloy fuel after a postulated LOCA. Since the cladding the licensee is proposing to use falls outside the definition of Zircaloy, the licensee requested exemptions from 10 CFR 50.44, 10 CFR 50.46, and appendix K to 10 CFR part 50. The Commission believes that special circumstances exist to grant the exemption requests since application of the rules at issue here would not achieve the underlying purpose of those rules. The underlying purpose of 10 CFR 50.46 and appendix K to 10 CFR part 50 is to establish requirements for emergency core cooling systems. The underlying purpose of 10 CFR 50.44 is to control hydrogen generated by the metal/water reaction after a postulated LOCA, regardless of whether that metal is Zircaloy or ZIRLO. The licensee addressed the safety impact of using the new fuel in its amendment and exemption application, and the staff had previously evaluated a similar impact in its Safety Evaluation of Topical Report WCAP-12610, "Vantage+ Fuel Assembly Reference Core Report," dated July 1, 1991, and supplemented October 9, 1991. These evaluations concluded that a facility can continue to comply with the purpose of the appropriate regulation with ZIRLO clad fuel.

Environmental Impacts of the Proposed Action

The proposed exemptions do not increase the probability or consequences of accidents previously analyzed, and do not affect radiological plant effluents. The new fuel assemblies meet the same design bases as the fuel that is currently in the reactor. No safety limits have been changed or setpoints altered as a result of the use of these new assemblies. The FSAR analyses are bounding for the new assemblies, as well as for the rest of the core. The advanced zirconium-based alloys have been shown through testing to perform satisfactorily under conditions representative of a reactor environment and the material properties of ZIRLO and Zircaloy are very similar. Issuance of the exemptions does not involve a significant increase in the allowable individual or cumulative occupational radiation exposure. Accordingly, the Commission concludes that issuing the exemptions would result in no significant radiological environmental impacts.

With regard to potential nonradiological impacts, the proposed exemptions involve fuel cladding only. They do not affect nonradiological plant effluents and have no other environmental impact. Therefore, the Commission concludes that there are no significant nonradiological environmental impacts associated with the proposed exemptions.

Alternatives to the Proposed Action

Since the Commission has concluded that there are no significant environmental effects that would result from the proposed action, any alternatives with greater or equal environmental impacts need not be evaluated. The principal alternative would be to deny the licensee's amendment and exemption requests. This would not reduce environmental impacts of plant operations.

Alternative Use of Resources

This action does not involve the use of resources not previously considered in the "Final Environmental Statement Related to the Operation of Indian Point Nuclear Generating Plant Unit No. 3," dated February 1975.

Agencies and Persons Consulted

The staff reviewed the licensee's request and did not consult other agencies or persons.

Finding of No Significant Impact

Based on the foregoing environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the Commission has determined not to prepare an environmental impact statement for the exemptions under consideration.

For further details with respect to this action, see the application for exemptions dated January 8, 1992, as supplemented February 26, 1992. These documents are available for public inspection at the Commission's Public Document Room, 2120 L Street, NW., Washington, DC, and at the White Plains Public Library, 100 Martine Avenue, White Plains, New York 10610.

Dated at Rockville, Maryland, this 21 day of April 1992.

For the Nuclear Regulatory Commission.

Robert A. Capra,

Director, Project Directorate I-I, Division of Reactor Projects-I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 92-9830 Filed 4-27-92; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-336]

Northeast Nuclear Energy Co.; Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. DPR-65 issued to Northeast Nuclear Energy Company (the licensee) for operation of the Millstone Nuclear Power Station, Unit No. 2, located in New London County, Connecticut.

The proposed amendment would modify the existing two region spent fuel pool design of Millstone, Unit No. 2, modified by amendment 109, dated January 15, 1986, and amendment 128, dated March 31, 1988, to a three region configuration.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The proposed change does not involve a significant hazards consideration because the change would not:

1. Involve a significant increase in the probability or consequences of an accident previously evaluated.

Radiological consequences of the fuel handling accident are not impacted by the formation of Regions A and B because the fuel assembly design is unchanged. However, the probability of occurrence of a fuel misplacement error has increased slightly. The increase is not significant because the types of controls being put into place in Regions A and B are of the same type as already in place in Region C. Furthermore, a fuel assembly misplacement error is not considered an accident, as defined in the Final Safety Analysis Report.

2. Create the possibility of a new or different kind of accident from any previously evaluated.

No changes are being made to the fuel assemblies or the storage racks, and controls used in the fuel pool will be of the same type as are now in place. As such, there is no possibility of a new or different kind of accident being created. The existing design basis covers all possible accident scenarios in the spent fuel pool.

3. Involve a significant reduction in a margin of safety.

There is no reduction in the margin of safety since Keff [less than or equal to] 0.95 is met under all analyzed conditions using conservative assumptions which do not credit the soluble boron in the spent fuel pool except under some accident conditions, as allowed by NRC guidelines. The original mechanical analyses are unchanged for thermal and seismic/structural considerations.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within thirty (30) days after the date of publication of this notice will be considered in making any final determination. The Commission will not normally make a final determination unless it receives a request for a hearing.

Written comments may be submitted by mail to the Rules and Directives Review Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of the **Federal Register** notice. Written comments may also be delivered to Room P-223, Phillips Building, 7920 Norfolk Avenue, Bethesda, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555. The filing of requests for hearing and petitions for leave to intervene is discussed below.

By May 28, 1992, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555 and at the local public document room located at the Learning Resources Center, Thames Valley State Technical College, 574 New London Turnpike, Norwich, Connecticut 06360. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made party to the proceeding; (2) the nature and extent of the petitioner's

property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1-(800) 325-6000 (in Missouri 1-(800) 342-6700). The Western Union Operator should be given Datagram Identification Number 3737 and the following message addressed to John F. Stolz: petitioner's name and telephone number, date petition was mailed, plant name, and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to Gerald Garfield, Esquire, Day, Berry & Howard, City Place, Hartford, Connecticut 06103-3499, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)-(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated April 16, 1992, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555 and at the local public document room located at the Learning Resources Center, Thames Valley State Technical College, 574 New London Turnpike, Norwich, Connecticut 06360.

Dated at Rockville, Maryland, this 21st day of April 1992.

For the Nuclear Regulatory Commission.

Guy S. Vissing,

Senior Project Manager Project Directorate I-4, Division of Reactor Projects-I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 92-9833 Filed 4-27-92; 8:45 am]

BILLING CODE 7590-01-M

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Committee on Life Sciences and Health/Federal Coordinating Council for Science, Engineering and Technology; Federally Funded Genome Research: Science and Technology Transfer Issues

AGENCIES: Department of Agriculture, Department of Commerce, Department of Energy, Department of Health and Human Services, Department of State, National Science Foundation, and Office of Science and Technology Policy.

ACTION: Notice of public meeting.

SUMMARY: This is an announcement of a public meeting to be held on May 21-22, 1992, in Washington DC to discuss science and technology transfer issues related to Federally funded genome research. The meeting is sponsored by the U.S. Department of Agriculture (USDA), the Department of Commerce (DOC), the Department of Energy (DOE), the Department of Health and Human Services (DHHS), the Department of State (DOS), the National Science Foundation (NSF), the Office of Science and Technology Policy (OSTP). These Departments and Agencies are members of an interagency committee "the Genome Patent Working Group", formed

under the Committee on Life Sciences and Health/Federal Coordinating Council for Science, Engineering and Technology.

The purpose of the public meeting is primarily educational: (1) to inform the interested public about the U.S. intellectual property protection system and technology transfer laws as applied to genome research and its products, and (2) to gather information from the interested public about its views and concerns related to scientific and technology transfer issues arising from Federally funded genome research.

The Genome Patent Working Group (GPWG) seeks diverse perspectives from a broad range of organizations and individuals including scientists in academia, industry and government laboratories; trade associations; professional societies; international organizations; and other interested individuals and organizations.

DATES AND ADDRESS: The meeting will be held on May 21 and 22, 1992, in the auditorium of the National Academy of Sciences in Washington DC Attendees should use the entrance at 2100 C Street NW. The meeting will begin at 8:30 a.m., and is expected to last till 5 p.m. on May 21, and 12 Noon on May 22, with registration from 8 a.m. to 8:30 a.m. on both days. Members of the public are invited to attend.

HOW TO REGISTER: To register to attend the meeting, contact Sandra Beaulieu, Science/Engineering Education Division, Oak Ridge Associated Universities, P.O. Box 117, 200 Badger Avenue, Oak Ridge, Tennessee 37831–0117, at (615) 576–7393, by May 14, 1992. Advance registration is desirable for those who wish to make oral presentations. On-site registration will also be held on the days of the meeting from 8 a.m. to 8:30 a.m.

Individuals wishing to make oral presentations (limited to 3 minutes) should submit their names, affiliations, addresses, and a general topic area for their comments to Sandra Beaulieu at the above address, or fax the information to her at (615) 576–0202, by May 14, 1992. Representatives of organizations wishing to make oral presentations (limited to 5 minutes) should submit their names, the names and addresses of organizations represented, and a general topic area for their comments to the same. Oral presenters may submit additional written comments as well. From those who are not able to attend the meeting, written comments (not more than 5 pages) will be accepted by the Oak Ridge Associated Universities until May 19, 1992. Comments should be mailed or FAXed to Sandra Beaulieu.

Because of the limited time for oral presentations, presenters will be accommodated to the extent possible; all presentations, whether oral or written, will be given full consideration by the GPWG. A full public record will be created to contain all comments, written and oral, submitted to the GPWG. Individuals and groups with similar comments are asked to consolidate comments into single remarks to the extent possible.

FOR FURTHER INFORMATION CONTACT: Dr. Machi F. Dilworth, National Science Foundation, 202/357–7652.

SUPPLEMENTARY INFORMATION: The GPWG is preparing a document "Intellectual Property Protection and Genome Research: Background Information for a Public Meeting" as background material for the public meeting. Individuals and organizations responding to this **Federal Register** announcement will be sent a copy of this document from Sandra Beaulieu at the address, phone and fax numbers listed in the "HOW TO REGISTER" section above.

The document contains brief descriptions of the scientific background on genome research, various means of protecting intellectual property, pertinent laws on patenting and licensing, and how various Federal agencies promote technology transfer activities. It also lists issues and questions on which the GPWG members are particularly interested in obtaining public comments. Responders are encouraged to read Section VII "ISSUES AND QUESTIONS" of the document for specific questions. In addition, the GPWG would welcome any comments on issues that are not identified in the document but are pertinent to the subject in question.

Dated: April 22, 1992.

Mary E. Clutter,

Chair, Genome Patent Working Group.

Dated: April 22, 1992.

James O. Mason,

Chair, Committee on Life Sciences and Health.

Dated: April 22, 1992.

D. Allan Bromley

Chair, Federal Coordinating Committee for Science, Engineering and Technology

(FR Doc. 92–9749 Filed 4–27–92; 8:45 am)

BILLING CODE 7555–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-30605; File No. SR-PTC-92-03

Self-Regulatory Organizations; Participants Trust Company; Filing of Proposed Rule Change Relating to the Adoption of a New Procedure to Provide for the Processing of Financing Transactions Through Its Collateral Loan Facility

April 20, 1992

Pursuant to section 19(b) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b), notice is hereby given that on March 20, 1992, the Participants Trust Company ("PTC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change adopts a new procedure to provide for the processing of financing transactions through PTC's collateral loan facility ("CLF").

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, PTC included statements concerning the purpose of and basis for the proposed rule charge and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. PTC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule filing is to provide for the processing of financing transactions which involve interests in large quantities of GNMA pools utilizing certain operational aspects of PTC's CLF and pledgee accounts

1. Bulk Movements for Financing Transactions

In the GNMA market, some financing transactions are part secured loan (involving pledges of securities as collateral) and part repurchase agreement ("repo"). These transactions often involve large quantities of securities. Under PTC's Rules and processing system, securities which are pledged can be transferred in large quantities, *i.e.*, in bulk, while securities underlying repo agreements can only be moved one pool at a time. Accordingly, it is desirable for PTC to facilitate the bulk movement of securities involved in such transactions without PTC's Rules characterizing the transactions as either a pledge or a repo. This would permit the parties to accomplish such characterization and the concomitant legal implications by contract outside of PTC's Rules. PTC will refer to these transactions as bulk financing transfers ("BFTs") and the securities involved in a BFT as "BFT Securities."

2. Use of CLF for Financing Transactions

PTC will use its CLF to process BTFs, except that a BFT would transfer the entire interest in the securities, as opposed to a security interest in the securities as is the case under a regular CLF transfer. Under the proposal, a delivering participant [1] would utilize the the CLF, but would enter a special code which would identify the transfer as a BFT. The BFT designation by the delivering participant and the acceptance of a BFT by a receiving participant would constitute a representation by both parties that the transfer reflects a financing transaction. Use of this BFT code will have the legal effect of transferring the entire interest in the securities, not a limited interest.

The CLF allows a participant to make a bulk transfer of securities to a pledgee account, eliminating the need to create individual pool-by-pool book-entry movements. The CLF also allows the delivering participant to retain the right to receive principal and interest ("P&I") payments. Thereafter, the securities access command ("SAC") allows the receiving participant to receive the P&I. In addition, after execution of the SAC, the securities can be withdrawn or retransferred to another account (either free or versus payment), thus providing the receiving participant with the attributes of possession of the pledged securities.

[1] In a BFT, although the pledge accounts are used, participants delivering or receiving securities are not referred to as pledge or pledgee participants, but rather as delivering or receiving participants.

3. P&I and retransfer for BFTs

Since the CLF technology will be utilized, the delivering participant will be credited with the P&I, subject to the ability of the receiving participant to exercise the SAC, giving the receiving participant (or successive transferees) the right to receive the P&I.

In addition, upon execution of a SAC, the BFT securities will, like pledged securities, be transferable by the receiving participant. However, the outside agreements between the delivering and receiving participant governing the terms of the BFT, and not PTC's Rules, will determine the subsequent rights of the original delivering participant.

4. BFT for Repo

To the extent that BFTs include repo transactions, the use of the CLF parallels and will provide participants with, in effect, the same attributes of PTC's repo accounting facility, although not specifically characterizing the transaction as a repo. Specifically, in the repo accounting facility, the repo seller is credited with the equivalent of P&I. Similarly, in a BFT, the delivering participant is credited with the P&I, subject to the receiving participant's ability to obtain the P&I by exercising the SAC. The repo accounting facility also accommodates repo secondary transactions (*i.e.*, where the original repo buyer resells securities to a participant other than the original repo seller). Under a BFT, receiving participant would, by exercising the SAC, in effect, acquire the attributes of possession of the securities with the corresponding ability to re-transfer them in a repo secondary transaction. Finally, the procedures for closing out a repo accounting record allow the repo buyer to request a closeout upon representation to PTC that its obligation to resell is terminated.[2] Since PTC has no duty to verify that the obligation is, in fact, terminated, this is comparable to a BFT where the receiving participant can, in effect, obtain the attributes of possession of BFT securities by unilateral exercise of the SAC, subject to any rights of the delivering participant under outside agreements.

5. PTC to Continue to Consider Systems Changes To Accommodate BFTs

PTC believes that, at the present time, the use of the CLF technology, with the proposed rule change to re-characterize the transaction as a transfer of the entire interest in the securities, is an efficient and economical use of existing capabilities to accommodate its participants for these transactions. PTC's software vendor has advised that modifying the existing repo accounting facility to achieve bulk movement capability will be time-consuming and costly. PTC intends, however, to continue to review its Rules and the functional capacity of its processing system to determine if more-encompassing changes can and should be made to accommodate this and related aspects of securities pledges and repo transactions.

[2] Securities Exchange Act Release No. 29617 (August 27, 1991), 56 FR 43827.

Since the proposed rule change promotes the prompt and accurate clearance and settlement of securities transactions, PTC believes that it is consistent with the requirements of Section 17A of the Act and the rules and regulations thereunder applicable to PTC. PTC believes that the proposed rule change will be implemented consistently with the safeguarding of securities and funds in PTC's custody or control or for which it is responsible since the proposed rule change will be implemented within PTC's existing safeguards.

B. Self-Regulatory Organization's Statement on Burden on Competition

PTC does not believe that the proposed rule change will have an impact on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

PTC has not solicited, and does not intend to solicit, comments on this proposed rule change. PTC has not received any unsolicited written comments from participants or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within thirty-five days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to ninety days of such date if it finds such longer period to be appropriate and publishes its reason for so finding or (ii) as to which the self-regulatory consents, the Commission will:

(A) By order approve such proposed rule change or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of PTC. All submissions should refer to File No. SR-PTC-92-03 and should be submitted by May 19, 1992.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland

Deputy Secretary.

[FR Doc. 92-9871 Filed 4-27-92; 8:45 am]

BILLING CODE 8010-01-M

[Rel. No. IC-18665; 811-4562]

DR European Equity Fund Inc.; Notice of Application

April 20, 1992.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of Application for Deregistration under the Investment Company Act of 1940 (the "Act").

APPLICANT: DR European Equity Fund Inc.

RELEVANT ACT SECTION: Section 8(f).

SUMMARY OF APPLICATION: Applicant seeks an order declaring that it has ceased to be an investment company under the Act.

FILING DATE: The application on Form N-8F was filed on March 19, 1992.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on May 15, 1992, and should be accompanied by proof of service on applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street NW., Washington, DC 20549. Applicant, 535 Madison Avenue, New York, New York 10022.

FOR FURTHER INFORMATION CONTACT: Robert A. Robertson, Staff Attorney, at (202) 504-2283, or C. David Messman, Branch Chief, at (202) 272-3018 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch.

Applicant's Representations

1. Applicant is a Maryland corporation registered as an open-end investment company under the Act. On January 17, 1986, applicant, which then was named The France Fund, Inc., filed a notification of registration on Form N-8A. On the same date, applicant filed a registration statement on Form N-2 under the Act and the Securities Act of 1933 (the "Securities Act") in order to register shares as a closed-end investment company. Such registration statement became effective on May 30, 1986, and applicant's initial public offering commenced on June 2, 1986. On September 6, 1989, applicant filed a registration statement on Form N-1A under the Act and the Securities Act in order to register shares as an open-end investment company. Such registration statement became effective on December 11, 1989, and the shares were publicly offered beginning on that day. Applicant changed its name to DR European Equity Fund Inc. on January 10, 1990.

2. On November 11, 1991, applicant's Board of Directors, determined that it was in the best interest of applicant's shareholders for applicant to enter into a reorganization (the "Reorganization") with National Worldwide Opportunities Fund ("Worldwide"). A combined proxy statement and prospectus was mailed to applicant's shareholders, and was filed with the SEC on December 10, 1991. Applicant's shareholders approved the Reorganization at a special meeting held on February 25, 1992. The Reorganization was consummated as of the close of business on February 26, 1992. All of applicant's assets and liabilities were transferred to Worldwide in exchange for shares of Worldwide having an equal aggregate value. These Worldwide shares then were distributed to applicant's shareholders in complete liquidation of applicant. Each of applicant's shareholders received shares of Worldwide of equal aggregate value to the shares of applicant held by such shareholder at the time of the Reorganization.

3. Expenses associated with the Reorganization totaled approximately $99,900, consisting principally of legal and audit fees, and proxy printing and solicitation expenses. Of this amount, $50,000 was paid by National Securities & Research Corporation, Worldwide's manager, and the balance was paid by applicant.

4. Articles of Transfer were filed with the State of Maryland to effect the Reorganization. Articles of Dissolution will be filed in accordance with Maryland law as soon as practicable.

5. Applicant has no shareholders and no assets. Applicant is not a party to any litigation or administrative proceeding. Applicant is not presently engaged, nor does it propose to engage in, any business activities other than those necessary for the winding up of its affairs.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 92-9869 Filed 4-27-92; 8:45 am]

BILLING CODE 8010-01-M

[Rel. No. IC-18667; 811-3840]

Wells Fargo Investment Trust For Retirement Programs; Application for Deregistration

April 21, 1992.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of Application for Deregistration under the Investment Company Act of 1940 ("Act").

APPLICANT: Wells Fargo Investment Trust For Retirement Programs.

RELEVANT ACT SECTION: Section 8(f).

SUMMARY OF APPLICATION: Applicant seeks an order declaring that it has ceased to be an investment company.

FILING DATE: The application on Form N-8F was filed on April 2, 1992.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a

hearing by writing to the SEC's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on May 18, 1992, and should be accompanied by proof of service on the applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. persons may request notification of a hearing by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicant, 525 Market Street, suite 1200, San Francisco, California 94163.

FOR FURTHER INFORMATION CONTACT: Barry A. Mendelson, Staff Attorney, at (202) 504-2284, or C. David Messman, Branch Chief at (202) 272-3018 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch.

Applicant's Representations

1. Applicant is an open-end diversified management investment company organized as a California collective investment trust. On September 8, 1983, applicant filed a Notification of Registration on Form N-8A and a registration statement on Form N-1A. The registration statement became effective on February 1, 1984, and applicant's initial public offering commenced on February 10, 1984.

2. Applicant is composed of six series: the Corporate Stock Fund, Asset Allocation Fund, Fixed Income Strategy Fund, Select Stock Fund, Ginnie Mae Fund, and Short Term Strategy Fund (the "Funds").

3. At a meeting held on September 18 and 27, 1991, applicant's board of directors unanimously approved an Agreement and Plan of Reorganization ("Agreement") among applicant, Stagecoach Funds, Inc., a Maryland corporation ("Stagecoach"), Stephens Inc., a Delaware corporation, and Well Fargo Bank, N.A. Proxy materials describing the Agreement were filed with the Commission on Form N-14 on October 21, 1991, and amended on November 29, 1991. The proxy materials were distributed to unitholders of each Fund on or about December 2, 1991. Unitholders owning a majority of the outstanding units of each Fund as of November 8, 1991 approved the reorganization at a special meeting held on December 31, 1991.

4. Pursuant to the Agreement, on January 2, 1992, applicant transferred substantially all of the assets of each of the Funds, and certain identified liabilities, to a corresponding series of Stagecoach (the "Stagecoach Funds"). In consideration therefor, each Stagecoach Fund delivered to the corresponding Fund the number of full and fractional shares of common stock of the Stagecoach Fund having an aggregate net asset value equal to the aggregate net asset value of the assets and liabilities transferred. No brokerage commissions were paid in connection with such exchange. On the same date, each Fund made a *pro rata* liquidating distribution to its shareholders of the shares it had received of the corresponding Stagecoach Fund.

5. Applicant ceased legal existence under California law on January 2, 1992 upon the transfer of its assets and liabilities to the Stagecoach Funds pursuant to the Agreement. Applicant intends to file a final Form N-SAR reflecting the winding up of its affairs.

6. Expenses applicable to the reorganization of the Funds are estimated to be approximately $738,000, all of which has been or will be paid by Well Fargo Bank, N.S. or Stephens Inc.

7. As of the date of the application, applicant had no securityholders, assets, or liabilities. Applicant is not a party to any litigation or administrative proceeding. Applicant is not presently engaged in, nor does it propose to engage in any business activities other than those necessary for the winding up of its affairs.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland.

Deputy Secretary.

[FR Doc. 92-9870 Filed 4-27-92; 8:45 am]

BILLING CODE 8010-01-M

SMALL BUSINESS ADMINISTRATION

[Declaration of Economic Injury Disaster Loan Area #7617]

New York; Declaration of Disaster Loan Area

Suffolk County and the contiguous county of Nassau in the State of New York constitute an Economic Injury Disaster Loan Area due to damages caused by fires which occurred on January 19 and 27, 1992 in the Town of Islip. Eligible small businesses without credit available elsewhere and small agricultural cooperatives without credit available elsewhere may file applications for economic injury assistance until the close of business on January 14, 1993 at the address listed below: U.S. Small Business Administration, Disaster Area 1 Office, 360 Rainbow Blvd., South, 3rd Fl., Niagrara Falls, NY 14303; or other locally announced locations. The interest rate for eligible small businesses and small agricultural cooperatives is 4 percent.

(Catalog of Federal Domestic Assistance Program No. 59002.)

Dated: April 14, 1992.

Paul H. Cooksey,

Acting Administrator.

[FR Doc. 92-9813 Filed 4-27-92; 8:45 am]

BILLING CODE 8025-01-M

[Declaration of Economic Injury Disaster Loan Areas #7618 & #7619]

Washington; (And Contiguous Counties in Idaho) Declaration of Disaster Loan Area

Whitman County and the contiguous counties of Adams, Asotin, Columbia, Franklin, Garfield, Lincoln, Spokane, and Walla Walla in the State of Washington, and Benewah, Latah, and Nez Perce counties in the State of Idaho constitute an Economic Injury Disaster Loan Area due to damages caused by a fire which occurred on February 2, 1992 in the City of Pullman. Eligible small businesses without credit available elsewhere and small agricultural cooperatives without credit available elsewhere may file applications for economic injury assistance until the close of business on January 13, 1993 at the address listed below: U.S. Small Business Administration, Disaster Area 4 Office, P.O. Box 13795, Sacramento, CA 95853-4795; or other locally announced locations. The interest rate for eligible small businesses and small agricultural cooperatives is 4 percent.

(Catalog of Federal Domestic Assistance Program No. 59002.)

Dated: April 13, 1992.

Patricia Saiki,

Administrator.

[FR Doc. 92-9809 Filed 4-27-92; 8:45 am]

BILLING CODE 8025-01-M

Region IX Advisory Council Meeting

The U.S. Small Business Administration Region IX Advisory Council, located in the geographical area of Honolulu, will hold a public meeting at 9:30 a.m. on Thursday, May 21, 1992, at the Prince Kuhio Federal Building, 300 Ala Moana Boulevard, Conference Room 4113A, Honolulu, Hawaii, to

discuss such matters as may be presented by members, staff of the U.S. Small Business Administration, or others present.

For further information, write or call Mr. Andrew K. Poepoe, District Director, U.S. Small Business Administration, 300 Ala Moana Boulevard, room 2213, Honolulu, Hawaii 96850, (808) 541-2990.

Dated: April 21, 1992.

Caroline J. Beeson,

Assistant Administrator Office of Advisory Councils.

[FR Doc. 92-9812 Filed 4-27-92; 8:45 am]

BILLING CODE 8025-01-M

Region III Advisory Council Meeting

The U.S. Small Business Administration Region III Advisory Council, located in the geographical area of Baltimore, will hold a public meeting from 9 a.m. to 11 a.m. on Thursday, May 21, 1992, at 10 North Calvert Street, 3rd Floor, Baltimore, Maryland, to discuss such matters as may be presented by members, staff of the U.S. Small Business Administration, or others present.

For further information, write or call Mr. Charles J. Gaston, District Director, U.S. Small Business Administration, 10 North Calvert Street, 3rd Floor, Baltimore, Maryland 21202 (410) 962-2054.

Dated: April 20, 1992.

Caroline J. Beeson,

Assistant Administrator, Office of Advisory Councils.

[FR Doc. 92-9810 Filed 4-27-92; 8:45 am]

BILLING CODE 8025-01-M

Region III Advisory Council Meeting

The U.S. Small Business Administration Region III Advisory Council located in the geographical area of Richmond, will hold a public meeting from 9 a.m. to 2 p.m., on Tuesday, June 2, 1992 at the Federal Building, 400 North 8th Street, Room 7230, Richmond, Virginia, to discuss such matters as may be presented by members, staff of the U.S. Small Business Administration, or others present.

For further information, write or call Mr. Dratin Hill, Jr., District Director, U.S. Small Business Administration, P.O. Box 10126, Federal Building, Richmond, Virginia 23240, (804) 771-2400.

Dated: April 20, 1992.

Caroline J. Beeson,

Assistant Administrator, Office of Advisory Councils.

[FR Doc. 92-9811 Filed 4-27-92; 8:45 am]

BILLING CODE 8025-01-M

DEPARTMENT OF STATE

[Public Notice 1612]

Oceans and International Environmental and Scientific Affairs Advisory Committee; Partially Closed Meeting

The Antarctic Section of the Oceans and International Environmental and Scientific Affairs Advisory Committee will meet at 2 p.m., May 19, 1992, in room 1406, Department of State, 22nd and C Streets, NW., Washington, DC.

At this meeting, officers responsible for Antarctic affairs in the Department of State will report on the Protocol on Environmental Protection to the Antarctic Treaty, signed in Madrid on October 4, 1991 and the legislation necessary to implement it. The section will also discuss issues related to the Seventeenth Antarctic Treaty Consultative Meeting, which will be held in Venice, November 9-20, 1992 and current issues of the Commission for the Convention on the Conservation of Marine Living Resources (CCAMLR). Department officials will be prepared to discuss other key issues and problems involving the Antarctic in the context of current domestic and international developments. This session will be open to the public. The public will be admitted to the session to the limits of seating capacity and will be given the opportunity to participate in discussion according to the instructions of the Chairman. As access to the Department of State is controlled, persons wishing to attend the meeting should enter the Department through the Diplomatic ("C" Street) Entrance. Department officials will be at the Diplomatic Entrance to escort attendees.

The Antarctic Section of the Oceans and International Environmental and Scientific Affairs Advisory Committee will also meet on May 18, in room 1205, Department of State, 22nd and C Streets, NW. The purpose of these discussions will be to elicit views concerning the further development of United States policy regarding current Antarctic issues, and will concentrate on the Protocol on Environmental Protection to the Antarctic Treaty, signed in Madrid on October 4, 1991 and the legislation necessary to implement it. The Section will also discuss issues related to the Seventeenth Antarctic Treaty Consultative Meeting, which will be held in Venice, November 9-20, 1992 and current issues of the Commission for the Convention on the Conservation of Marine Living Resources (CCAMLR). The meeting will include classified briefings and examination and discussion of classified documents pursuant to Executive Order 12356. The disclosure of classified material and revelation of considerations which go into policy development would substantially undermine and frustrate the U.S. position in future meetings and negotiations. Therefore, the meeting will not be open to the public, pursuant to section 10(d) of the Federal Advisory Committee Act and 5 U.S.C. 552b(c)(1) and 5 U.S.C. 552b(c)(9)(B).

Requests for further information on the meetings should be directed to R. Tucker Scully of OES/OA, Room 5801, Department of State. He may be reached by telephone on (202) 647-3262.

Dated: April 15, 1992.

Curtis Bohlen,

Chairman.

[FR Doc. 92-9760 Filed 4-27-92; 8:45 am]

BILLING CODE 4710-09-M

DEPARTMENT OF TRANSPORTATION

[Docket 37554]

Order Adjusting the Standard Foreign Fare Level Index

The International Air Transportation Competition Act (IATCA), Public Law 96-192, requires that the Department, as successor to the Civil Aeronautics Board, establish a Standard Foreign Fare Level (SFFL) by adjusting the SFFL base periodically by percentage changes in actual operating costs per available seat-mile (ASM). Order 80-2-69 established the first interim SFFL, and Order 92-2-10 established the currently effective two-month SFFI, applicable through March 31, 1992.

In establishing the SFFL for the two-month period beginning April 1, 1992, we have projected non-fuel costs based on the year ended December 31, 1991 data, and have determined fuel prices on the basis of the latest available experienced monthly fuel cost levels as reported to the Department.

By Order 92-4-39 fares may be increased by the following adjustment factors over the October 1979 level:

Atlantic	1.5956
Latin America	1.4322
Pacific	2.0112
Canada	1.4433

For further information contact: Keith A. Shangraw (202) 366-2439.

By the Department of Transportation: April 22, 1992

Pat V. Murphy,

Deputy Assistant Secretary for Policy and Program Development.

[FR Doc. 92-9873 Filed 4-27-92; 8:45 am]

BILLING CODE 4910-62-M

Announcement of Medical Review Officers Conference

AGENCY: Department of Transportation, Office of the Secretary.

ACTION: Notice of conference for medical review officers providing services for DOT regulated employers.

SUMMARY: The Department of Transportation (DOT) is sponsoring three conferences for physicians who currently provide or intend to provide medical review officer services for DOT regulated employers. This notice concerns the dates, locations, agenda, and registration information for the conferences.

DATES: The conferences will be held in three cities, Washington, DC; Chicago, Illinois; and San Francisco, California. The Washington conference is scheduled for June 10–11, 1992; Chicago for June 16–17, 1992 and San Francisco for June 29–30, 1992.

FOR FURTHER INFORMATION CONTACT: Mr. Perry Chipps, Exhibit Conference Director, U.S. Department of Transportation, Volpe National Transportation Systems Center, 55 Broadway, Kendall Square, Cambridge, MA 02142, Telephone: 617–494–2583.

SUPPLEMENTARY INFORMATION: In November 1988, the Department of Transportation (DOT) published regulations requiring drug testing programs in the aviation, maritime, railroad, mass transit, pipeline, and motor carrier industries. Employers in these industries should have begun drug testing no later than December 1990. The Department believes that continued information dissemination and technical assistance to people involved in the implementation of the DOT anti-drug rules are critical to effective workplace drug testing programs. An essential component of the DOT-mandated drug testing programs is the role of the Medical Review Officer (MRO). The MRO is a licensed physician with knowledge of substance abuse disorders, employed by the transportation company, or a private physician retained for this purpose. The MRO's primary functions are the receipt, review and interpretation of tests results.

These conferences are designed to provide a forum for discussion and interaction with DOT and other government officials concerning the DOT drug testing rules as they relate to medical review officer functions. Each conference will include presentations designed to provide further clarification of the duties and responsibilities of the MRO as outlined in 49 CFR part 40. The conferences are planned to present panel discussions and dialogue in an effort to foster an exchange of ideas and experiences in effective implementation of the Department's drug testing regulations.

Each conference will be two days in length. The conference agenda will include technical discussions of amphetamine and opiate positives, program issues related to administrative review of test results, criteria for invalid results, notification procedures, and case study presentations.

Additionally, representatives from the DOT agencies will facilitate sessions on MRO recordkeeping, reporting, and return-to-duty responsibilities as defined in each of the DOT agency rules.

Conference participation is limited to 300 attendees. Professional staff, assisting physicians in their MRO duties, may also attend. The conference registration fee will be $95.00 per person. All conference attendees are responsible for their own travel, lodging, and incidental expenses. Special conference hotel rates have been arranged, details are available from the Conference Management firm listed below.

For registration materials and information, you should contact: Mr. Perry Chipps, Exhibit Conference Director, U.S. Department of Transportation, Volpe National Transportation Systems Center, 55 Broadway, Kendall Square, Cambridge, MA 02142, Telephone: 1–800–336–4583 Extension 6207, (for Virginia area code 703, dial 703–631–6207). FAX: 703–818–9177.

Issued this 22d day of April 1992, at Washington, DC.

Robert A. Knisely,

Special Assistant to the Secretary for Drug Enforcement and Program Compliance, Department of Transportation.

[FR Doc. 92–9872 Filed 4–27–92; 8:45 am]

BILLING CODE 4910–62–M

Federal Highway Administration

Environmental Impact Statement: Hillsborough and Rockingham Counties, NH

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an environmental impact statement (EIS) will be prepared for a proposed highway project in Hillsborough and Rockingham Counties, New Hampshire.

FOR FURTHER INFORMATION CONTACT: Mr. William F. O'Donnell, P.E., Area Engineer, Federal Highway Administration, 279 Pleasant Street, room 204, Concord, New Hampshire 03301, Telephone: (603) 225–1608, or Mr. William R. Hauser, Supervisor, Environmental Services Section, New Hampshire Department of Transportation, P.O. Box 483, John O. Morton Building, Concord, New Hampshire 03302–0483, Telephone: (603) 271–3226.

SUPPLEMENTARY INFORMATION: The FHWA in cooperation with the New Hampshire Department of Transportation (NHDOT), will prepare an environmental impact statement (EIS) for a proposal for construction on a section of an existing highway facility (I–93 extending from the Massachusetts/New Hampshire State Line in Salem to just south of Exit 6 in Manchester) that serves as the major transportation link for the State of New Hampshire.

The proposed action would relieve traffic congestion, reduce travel time, improve safety and accommodate projected increases in traffic demand.

Alternatives to be considered include (1) taking no action; (2) upgrading the existing route (approximately 18 miles in length) to add capacity, reduce travel time and/or improve safety; (3) constructing high occupancy vehicle lanes to facilitate an increased number of travelers while limiting demand as well as other Transportation Demand Management (TDM) measures such as car pool parking lots; (4) constructing mass transportation facilities in or adjacent to the existing corridor; and (5) combinations of these alternatives. Various designs of grade, alignment, geometry and access will be evaluated.

An Advisory Task Force will be established with representation from the regional planning agencies, state and local officials, business and industry and local citizens.

Letters describing the proposed action and soliciting comments will be sent to appropriate federal, state and local agencies, and to private organizations and citizens who have previously expressed or are known to have interest in this proposal. Public informational, community and Advisory Task Force meetings will be held in the study area as the project progresses in order to include public input in the planning process. A public hearing will be held following distribution of the Draft Environmental Impact Statement (DEIS). Public notice will be given regarding the time and location of this hearing. The DEIS will be available for review and

comment by the public and interested agencies prior to the public hearing.

A formal scoping meeting will be held at 9:30 a.m. on May 19,1992, in room 3 of the John O. Morton Building in Concord, New Hampshire to (1) confirm the limits of the project study area; (2) help to establish the study framework and the impacts to be analyzed; and (3) help to define a reasonable range of alternatives to be considered.

Agencies to be invited to be cooperating agencies are the U.S. Army Corps of Engineers (ACOE), the U.S. Environmental Protection Agency (EPA), the New Hampshire State Historic Preservation Office (SHPO) and the New Hampshire Wetlands Board.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments or questions concerning this proposal and the EIS should be directed to the FHWA or the NHDOT at the addresses provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on federal programs and activities apply to this program.)

Issued on: April 21, 1991.

Gerald L. Eller,

Division Administrator, Concord, New Hampshire.

[FR Doc. 92-9759 Filed 4-27-92; 8:45 am]

BILLING CODE 4910-22-M

National Highway Traffic Safety Administration

International Harmonization of Safety Standards; Calendar of Meetings

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Notice of meetings.

SUMMARY: The National Highway Traffic Safety Administration (NHTSA) will continue its participation during this year in the international meetings to harmonize U.S. and foreign motor vehicle safety standards. These meetings will be conducted by the Working Party on the Construction of Vehicles (WP29) under the Principal Working Party on Road Transport of the United Nations' Economic Commission for Europe (ECE), and by the six Meetings of Experts (formerly called Groups of Rapporteurs) of WP29. The NHTSA currently represents the United States in all of the Meetings of Experts except those on Pollution and on Noise.

DATES: For a list of scheduled meetings, see the Supplementary Information section of this Notice. Inquiries or comments related to specific meetings should be made to the addressee below at least two weeks preceding that meeting.

FOR FURTHER INFORMATION CONTACT: Francis J. Turpin, Office of International Harmonization (NOA-05), National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC. 20590 (202-366-2114).

SUPPLEMENTARY INFORMATION: This calendar consists of those ECE meetings currently scheduled. It is published for information and planning purposes and the meeting dates and places are subject to change. NHTSA attendance at these meetings will be affected by agenda content, priorities and availability of travel funds.

April 27-29, 1992:
- Meeting of Experts on Noise(GRB), Nineteenth Session—Geneva, Switzerland.

May 18-20, 1992:
- Meeting of Experts on Lighting and Light-Signalling(GRE), Twenty-Eighth Session—Geneva, Switzerland.

June 1-4, 1992:
- Meeting of Experts on Passive Safety(GRSP), Eleventh Session—Geneva, Switzerland.

June 22, 1992:
- Administrative Committee for the Coordination of Work of WP29(AC.2), Forty-Ninth Session—Geneva, Switzerland.

June 23-26, 1992:
- Working Party on the Construction of Vehicles(WP-29), Ninety-Seventh Session—Geneva, Switzerland.

July 13-15, 1992:
- Meeting of Experts on Brakes and Running Gear(GRRF), Thirty-First Session—Geneva, Switzerland.

August 26-28, 1992:
- Meeting of Experts on Pollution and Energy(GRPE), Twenty-Fifth Session—Geneva, Switzerland.

September 7-9, 1992:
- Meeting of Experts on Noise(GRB), Twentieth Session—Geneva, Switzerland.

October 12, 1992:
- Administrative Committee for the Coordination of Work of WP29(AC.2), Fiftieth Session—Geneva, Switzerland.

October 13-16, 1992:
- Working Party on the Construction of Vehicles(WP-29), Ninety-Eighth Session—Geneva, Switzerland.

November 9-12, 1992:
- Meeting of Experts on Lighting and Light-Signalling(GRE), Twenty-Ninth Session—Geneva, Switzerland.

November 16-18, 1992:
- Meeting of Experts on General Safety Provisions(GRSG), Sixty-Third Session—Rome, Italy.

December 7-9, 1992:
- Meeting of Experts on Passive Safety(GRSP), Twelfth Session—Geneva, Switzerland

The following meetings took place earlier this year.

January 20-22, 1992:
- Meeting of Experts on Pollution and Energy(GRPE), Twenty-Fourth Session—Geneva, Switzerland.

February 10-13, 1992:
- Meeting of Experts on Brakes and Running Gear(GRRF), Thirtieth Session—Geneva, Switzerland.

March 9, 1992:
- Administrative Committee for the Coordination of Work of WP29(AC.2), Forty-Eighth Session—Geneva, Switzerland.

March 10-13 1992:
- Working Party on the Construction of Vehicles(WP-29), Ninety-Sixth Session—Geneva, Switzerland.

March 23-25, 1992:
- Meeting of Experts on General Safety Provisions(GRSG), Sixty-Second Session—Geneva, Switzerland.

Issued on April 22, 1992.

Barry Felrice,

Associate Administrator for Rulemaking.

[FR Doc. 92-9778 Filed 4-27-92; 8:45 am]

BILLING CODE 4910-59-M

DEPARTMENT OF THE TREASURY

Office of the Secretary

List of Countries Requiring Cooperation with an International Boycott

In order to comply with the mandate of section 999(a)(3) of the Internal Revenue Code of 1986, the Department of the Treasury is publishing a current list of countries which may require participation in, or cooperation with, an international boycott (within the meaning of section 999(b)(3) of the Internal Revenue Code of 1986).

On the basis of the best information currently available to the Department of the Treasury, the following countries may require participation in, or cooperation with, an international boycott (within the meaning of section 999(b)(3) of the Internal Revenue Code of 1986).

Bahrain
Iraq
Jordan

Kuwait
Lebanon
Libya
Oman
Qatar
Saudi Arabia
Syria
United Arab Emirates
Yemen, Republic of

Dated: April 20, 1992.

Fred T. Goldberg, Jr.,

Assistant Secretary for Tax Policy.

Alan J. Wilensky,

Deputy Assistant Secretary for Tax Policy.

[FR Doc. 92-9578 Filed 4-27-92; 8:45 am]

BILLING CODE 4810-25-M

Office of Thrift Supervision

Olympic Federal Savings Association; Replacement of Conservator With a Receiver

Notice is hereby given that, pursuant to the authority contained in subdivision (F) of section 5(d)(2) of the Home Owners' Loan Act, the Office of Thrift Supervision duly replaced the Resolution Trust Corporation as Conservator for Olympic Federal Savings Association, Berwyn, Illinois ("Association"), with the Resolution Trust corporation as sole Receiver for the Association on March 27, 1992.

Dated: April 22, 1992.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Corporate Secretary.

[FR Doc. 92-9792 Filed 4-27-92; 8:45 am]

BILLING CODE 6720-01-M

[AC-17; OTS No. 2302]

New London Savings and Loan Association, New London, WI; Final Action; Approval of Conversion Application

Notice is hereby given that on April 13, 1992, the Office of the Chief Counsel, Office of Thrift Supervision, acting pursuant to delegated authority to him, approved the application of New London Savings and Loan Association, New London, Wisconsin, for permission to convert to the stock form of organization. Copies of the application are available for inspection at the Information Services Division, Office of Thrift Supervision, 1776 G Street, NW., Washington, DC 20552, and the Office of Thrift Supervision, Central Regional Office, 111 East Wacker Drive, suite 800, Chicago, Illinois 60601-4360.

Dated: April 22, 1992.

Nadine Y. Washington,

Corporate Secretary.

[FR Doc. 92-9791 Filed 4-27-92; 8:45 am]

BILLING CODE 6720-01-M

UNITED STATES INFORMATION AGENCY

Culturally Significant Objects Imported for Exhibition; Determination

Notice is hereby given of the following determination: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985, 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978 (43 FR 13359, March 29, 1978), and Delegation Order No. 85-5 of June 27, 1985 (50 FR 27393, July 2, 1985), I hereby determine that the objects to be included in the exhibit, "Masterpiece from The National Gallery of Ireland" (see list) [1] imported from abroad for the temporary exhibition without profit within the United States are of cultural significance. The objects are imported pursuant to a long agreement with the foreign lender. I also determine that the temporary exhibition or display of the listed exhibit objects at the Art Institute of Chicago, Chicago, Illinois, beginning on or about May 6, 1992, to on or about August 9, 1992; at the Fine Art Museum of San Francisco, San Francisco, California, beginning on or about August 14, 1992, to on or about December 6, 1992; the Museum of Fine Arts, Boston, Massachusetts, beginning on or about January 13, 1993, to on or about March 28, 1993; and the IBM Gallery of Science and Art, New York, New York, beginning on or about April 27, 1993, to on or about June 29, 1993, is in the national interest.

Public notice of this determination is ordered to be published in the **Federal Register**.

Dated: April 22, 1992.

Alberto J. Mora,

General Counsel

[FR Doc. 92-9874 Filed 4-27-92; 8:45 am]

BILLING CODE 8230-01-M

Eastern German Young Leaders Projects

AGENCY: United States Information Agency.

[1] A copy of this list may be obtained by contacting Mr. R. Wallace Stuart of the Office of the General Counsel of USIA. The telephone number is 202/619-5078, and the address is room 700, U.S. Information Agency, 301 Fourth Street, SW., Washington, DC 20547.

ACTION: Notice—Request for proposals.

SUMMARY: The Bureau of Educational and Cultural Affairs, U.S. Information Agency, announces its intention to award up to three grants not to exceed $40,000 each to private not-for-profit organizations to conduct three projects for young leaders and professionals from the five new states ("Laender") of Germany (formerly the German Democratic Republic). All three are planned as 3- to 4-week travel/observation projects. The first will be a project for up to 10 media professionals on the role of the media in a democratic society. The second will be a project on the American political process for up to 10 state parliamentarians/political leaders from the eastern states. The third will be a project on higher eddcation for up to 10 university professors in the social sciences and humanities. The German Government will also provide $50,000 in supplementary funds for each project. Additionally, grantee organizations are expected to provide some cost-sharing.

DATES: Deadline for proposals: All copies must be received at the U.S. Information Agency by 5 p.m. Washington, DC. time on Friday, June 5, 1992. Faxed documents will not be accepted, nor will documents postmarked on June 5, 1992, but received at a later date. It is the responsibility of each grant applicant to ensure that proposals are recieved by the above deadline. Grants should begin September 1, 1992.

ADDRESSES: The original and twelve copies of the completed application, including required forms, should be submitted by the deadline to: U.S. Information Agency, Ref: Eastern German Young Leaders Projects, Office of Grants Management (E/XE), room 357, 301 4th Street SW., Washington, DC 20547.

FOR FURTHER INFORMATION CONTACT: Interested organizations or institutions should contact Ms. Bettye Stennis at the Youth Programs Division (E/VY), Office of International Visitors, Room 357, 301 4th Street SW., Washington, D.C. 20547, telephone 202-619-6299, to request detailed application packets, which include award criteria additional to this announcement, all necessary forms, and guidelines for preparing proposals, including specific budget preparation information.

SUPPLEMENTARY INFORMATION: Pursuant to the Bureau's authorizing legislation, programs must maintain a non-political character and should be balanced and representative of the diversity of

American political, social and cultural life.

Overview

All participants will be selected by USIS Germany in conjunction with two cooperating German institutions. The program is designed to promote mutual understanding between the people of the United States and the emerging leaders in the former German Democratic Republic. Of central concern are the philosophical underpinnings and structures of the American political, social, economic and educational systems and their comparison to German institutions. Critical societal problems and issues are of special interest to eastern Germans. The Agency would like programming for these particiants to highlight the diversity of approaches in the U.S. to solving them.

Guidelines

The first project, entitled "Media in a Democratic Society," is designed to introduce up to 10 eastern German journalists aged 25–40, selected by USIS Bonn and the German Government, to the American media (print, television, radio), in order to increase their understanding of the role of the free press in a democratic society. The project will preferably take place in late September and early October, 1992. In addition to programming in Washington, the participants should travel to selected areas of the U.S. to learn about media issues in various regions, visit media institutions and interact extensively with Americans. The election campaign should factor prominently in their program.

The second project, entitled "The American Political Process," will bring up to 10 eastern German state parliamentarians/political leaders aged 25–40 to the U.S. in October or November of 1992. The project should provide an introduction to federal, state and local systems of government in the U.S. and focus on political, social and economic issues that are on the public agenda. The political campaign will also be of interest to this group. The project should include visits to Washington, DC, a state capital and one or two other program sites.

The third project, entitled "Higher Education," is for university faculty aged 25–40. This project should take place in late November and early December, 1922. The project seeks to give them a firsthand look at America's system of higher education. It should focus primarily on 4-year colleges and universities, as well as an examination of the diversity of academic institutions and programs in post-secondary education.

Proposed Budget

The grantee organizations will be responsible for: development of a detailed itinerary and program, including an orientation; domestic travel arrangements; disbursement of per diem and allowances for the participants and escort/interpreters; and final evaluation. The USIA grant only covers partial costs of the project. USIA is withholding funds apart from the grant to pay the salaries of the State Department contract escort/interpreters. The German Government will pay for the international travel and transfer funds to the grantee organizations to pay for partial program costs. Contributions both cash and in-kind from the grantee organization will be a criterion in judging the merits of proposals submitted in this competition.

Applicants must submit a comprehensive line item budget. Detailed instructions for preparation of the budget are available in the application packet.

Review Process

USIA will acknowledge receipt of all proposals and will review them for technical eligibility. Proposals will be deemed ineligible if they do not adhere to the guidelines established herein and in the application packet. Ineligible proposals will not be considered for funding. Eligible proposals will be forwarded to panels of USIA officers for advisory review. All eligible proposals will also be reviewed by the appropriate geographic area office, and budget and contracts offices. Proposals may also be reviewed by the Agency's Office of General Counsel. Funding decisions are at the discretion of the Associate Director for Educational and Cultural Affairs. Final technical authority for grant awards resides with USIA's contracting officer.

Review Criteria

Technically eligible applications will be competitively reviewed according to the following criteria:

1. Quality of the Program Idea

Proposals should exhibit originality, substance, rigor, and relevance to Agency mission.

2. Program Planning

Detailed agenda and relevant work plan should demonstrate substantive rigor and logistical capacity. Agenda and plan should adhere to the program overview and guidelines described above.

3. Ability to Achieve Program Objectives

Objectives should be reasonable, feasible, and flexible. Proposals should clearly demonstrate how the institution will meet the program's objectives and plan.

4. Multiplier Effect/Impact:

Proposed programs should strengthen long-term mutual understanding, including maximum sharing of information and establishment of long-term institutional and individual linkages.

5. Value to U.S.-German Relations:

Assessment of USIA's geographic area desk, USIS/Germany and the German Government of the potential impact and significance of the proposed projects.

6. Institutional Capacity:

Proposed personnel and institutional resources should be adequate and appropriate to achieve the program or projects goals.

7. Institution's Track Record/Ability:

Proposals should demonstrate a track record of successful programs, including responsible fiscal management and full compliance with all reporting requirements for past Agency grants as determined by USIA's of Contracts (M/KG). The Agency will consider the past performance of prior grantees and the demonstrated potential of new applicants.

8. Follow-on Activities:

Proposals should provide a plan for continued follow-on activity (without USIA support) which insures that USIA supported programs are not in isolated events.

9. Evaluation Plan:

Proposals should provide a plan for evaluation by the grantee institution.

10. Cost-effectiveness:

The overhead and administrative components of grants, as well as salaries and honoraria, should be kept as low as possible. All other items should be necessary and appropriate.

11. Cost-sharing:

Prposals should maximize cost-sharing through other private sector support as well as institutional direct funding contributions.

Notice

The terms and conditions published in this RFP are binding and may not be

modified by any USIA representative. Explanatory information provided by the Agency that contradicts published language will not be binding. Issuance of the RFP does not constitute an award commitment on the part of the Government. Final awards cannot be made until funds have been fully appropriated by Congress, allocated and committed through internal USIA procedures.

Notification

All applicants will be notified of the results of the review process on or before July 15. Awarded grants will be subject to periodic reporting and evaluation requirements.

Dated: April 21, 1992.

Barry Fulton,

Deputy Associate Director, Bureau of Educational and Cultural Affairs.

[FR Doc. 92-9875 Filed 4-27-92; 8:45 am]

BILLING CODE 8230-01-M

Sunshine Act Meetings

Federal Register
Vol. 57, No. 82
Tuesday, April 28, 1992

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

DEPARTMENT OF DEFENSE

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

Meeting Notice

TIME AND DATE: Full Board 2:00 p.m., May 15, 1992.

PLACE: Uniformed Services University of the Health Sciences, room D3-001, 4301 Jones Bridge Road, Bethesda, Maryland 20814-4799.

STATUS: Open—under "Government in the Sunshine Act" (5 U.S.C. 552b(e)(3)).

MATTERS TO BE CONSIDERED: 2:00 p.m. Meeting—Board of Regents.

(1) Approval of Minutes—February 3, 1992; (2) Faculty Matters;

(3) Report—Admissions; (4) Financial Report; (5) Associate Dean for Graduate Medical Education; (6) Report—President, USUHS; (7) Comments—Members, Board of Regents; (8) Comments—Chairman, Board of Regents; (9) Reports of Subcommittees on Planning and Oversight; (10) Report of Dean's Search Committee;

New Business.

CONTACT PERSON FOR MORE INFORMATION: David S. Trump, M.D., Executive Secretary of the Board of Regents, 301/295-3886.

Dated: April 24, 1992.

Linda Bynum,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 92-10030 Filed 4-24-92; 3:21 pm]

BILLING CODE 3810-01-M

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 1:04 p.m. on Thursday, April 23, 1992, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters relating to certain financial institutions.

In calling the meeting, the Board determined, on motion of Director C.C. Hope, Jr. (Appointive), seconded by Director T. Timothy Ryan, Jr. (Office of Thrift Supervision), and concurred in by Vice Chairman Andrew C. Hove, Jr., Chairman William Taylor, and Director Stephen R. Steinbrink (Acting Comptroller of the Currency), that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(8), (c)(9)(A)(ii), and 552b(c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

The meeting was held in the Board Room of the FDIC Building located at 550-17th Street, N.W., Washington, DC.

Dated: April 23, 1992.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Deputy Executive Secretary.

[FR Doc. 92-9973 Filed 4-24-92; 11:19 am]

BILLING CODE 6714-0-M

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM: .

TIME AND DATE: 11:00 A.M., Monday, May 4, 1992.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED: .

1. Proposed Federal Reserve Service Automation Services compensation program.

2. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

3. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: April 24, 1992.

Jennifer J. Johnson

Associate Secretary of the Board.

[FR Doc. 92-10019 Filed 4-24-92; 2:42 pm]

BILLING CODE 6210-01-M

NUCLEAR REGULATORY COMMISSION

DATE: Weeks of April 27, May 4, 11, and 18, 1992.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Open and Closed.

MATTERS TO BE CONSIDERED:

Week of April 27

Wednesday, April 29

11:30 a.m.

Affirmation/Discussion and Vote (Public Meeting)

a. Revisions to Procedures to Issue Orders: Challenges to Orders that are Made Immediately Effective—10 CFR Part 2 (Tentative) (Postponed from April 24)

Week of May 4—Tentative

Friday, May 8

11:30 a.m.

Affirmation/Discussion and Vote (Public Meeting) (if needed)

Week of May 11—Tentative

Monday, May 11

8:30 a.m.

Discussion of Internal Management Issues (Closed—Ex. 2)

10:00 a.m.

Briefing on Status of Licensed Operator Requalification Program (Public Meeting)

Wednesday, May 13

12:00 noon

Affirmation/Discussion and Vote (Public Meeting) (if needed)

Week of May 18—Tentative

Wednesday, May 20

11:30 a.m.

Affirmation/Discussion and Vote (Public Meeting) (if needed)

Note: Affirmation sessions are initially scheduled and announced to the public on a time-reserved basis. Supplementary notice is provided in accordance with the Sunshine Act as specific items are identified and added to the meeting agenda. If there is no specific subject listed for affirmation, this means that no item has as yet been identified as requiring any Commission vote on this date.

To verify the Status of Meeting Call (Recording)—(301) 504-1292.

CONTACT PERSON FOR MORE INFORMATION: William Hill (301) 504-1661.

Dated: April 24, 1992.

William M. Hill, Jr.,

Office of the Secretary.

[FR Doc. 92-10013 Filed 4-24-92; 2:09 pm]

BILLING CODE 7590-01-M

Corrections

Federal Register
Vol. 57, No. 82
Tuesday, April 28, 1992

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA-935-DR]

California; Amendment to Major Disaster Declaration

Correction

In notice document 92-6306 appearing on page 9552 in the issue of Thursday, March 19, 1992, make the following corrections:

1. In the third column, the docket number should read as set forth above.

2. In the same column, under **NOTICE**, after the second paragraph, the Catalog of Federal Domestic Assistance No. should read "83.516 SIC, Disaster Assistance".

BILLING CODE 1505-01-D

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA-010-02-4333-02-241A]

Firearms Use Restriction and Closure Order Established; Squaw Leap Management Area, Hollister Resource Area, Bakersfield District, CA

Correction

In notice document 92-6368 appearing on page 9562 in the issue of Thursday, March 19, 1992, in the third column, the signature at the end of the document should read "Robert Beehler".

BILLING CODE 1505-01-D

SECURITIES AND EXCHANGE COMMISSION

[Securities and Exchange Act of 1934 Release No. 30537; File No. 600-25]

The Registration as a Clearing Agency of the Participants Trust Co.; Order Granting Approval of Registration Until March 31, 1993

Correction

In notice document 92-8134 beginning on page 12351 in the issue of Thursday, April 9, 1992, in the second column, the release number and subject heading should read as set forth above.

BILLING CODE 1505-01-D

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-30536; File No. SR-NYSE-91-42]

Self-Regulatory Organizations; New York Stock Exchange, Inc.; Order Approving Proposed Rule Change Relating to Amending NYSE Rule 758(b)(ii)(A) to Broaden the Limitations on Principal/Agency Trading by Competitive Options Traders and to Amend the NYSE's Minor Rule Violation Plan

Correction

In notice document 92-8136 beginning on page 12357 in the issue of Thursday, April 9, 1992, in the first column, the subject heading should read as set forth above.

BILLING CODE 1505-01-D

federal register

Tuesday,
April 28, 1992

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 2, et al.

Abbreviated New Drug Regulations; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 2, 5, 10, 310, 314, 320, and 433

[Docket No. 85N-0214]

RIN 0905-AB63

Abbreviated New Drug Application Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing final regulations for most of its requirements for abbreviated new drug applications (ANDA's). FDA published a proposed rule for ANDA's in the **Federal Register** of July 10, 1989 (54 FR 28872). These regulations implement title I of the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments). This final rule covers subjects such as ANDA content and format, approval and nonapproval of an application, and suitability petitions. This rule does not finalize the provisions of the proposed rule on patent certification and market exclusivity; FDA is still examining the issues pertaining to those provisions and will finalize them in a future edition of the **Federal Register**.

EFFECTIVE DATE: The regulations will become effective on June 29, 1992.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Center for Drug Evaluation and Research (HFD-362), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8049.

SUPPLEMENTARY INFORMATION:

I. Background

A. New Drug Approval: 1938 to 1962

In 1938, Congress passed the Federal Food, Drug, and Cosmetic Act (the act). The act created a premarket approval system for drug products that required applicants seeking drug product approval to submit a new drug application (NDA) to FDA. The NDA would contain information demonstrating, among other things, that the drug product was safe. The act also provided that an NDA would automatically become effective (i.e., the product could be lawfully marketed) within a fixed period unless the agency affirmatively refused to approve the application.

In addition to drug products that had an effective NDA, many products were marketed without effective applications. These products were identical, similar, or related to products with effective NDA's. The manufacturers of these products had concluded that their drug products were generally recognized as safe, or had received advisory opinions from FDA that an NDA was not required because the products were generally recognized as safe.

In 1962, Congress amended the drug approval provisions of the act to require affirmative approval to NDA's before marketing. The amendments required applicants to show that their products were both safe and effective (Pub. L. 87-781 (October 10, 1962)). Thus, on or after October 10, 1962, a person could not market a new drug without an approved NDA that contained sufficient safety information as well as substantial evidence establishing the drug's effectiveness for its intended uses.

The 1962 amendments also deemed NDA's that had become effective before October 10, 1962, to be approved. As with postenactment drugs, the 1962 amendments required these "pre-1962" drugs to be shown to be effective for their intended uses. Consequently, FDA began a program to evaluate the drugs that had been deemed approved to determine whether there was substantial evidence of their effectiveness. This systematic evaluation and the implementation of FDA's findings became known as the Drug Efficacy Study Implementation (DESI). Under DESI, FDA contracted with the National Academy of Sciences/National Research Council (NAS/NRC), which established expert panels to review available evidence of effectiveness and to provide recommendations to FDA. FDA considered the NAS/NRC panels' recommendations about the effectiveness of these DESI drugs, and announced its conclusions through **Federal Register** notices. These notices, known as DESI notices, contain the acceptable marketing conditions for the class of drug products covered by the notice.

B. The ANDA Procedure for Pre-1962 Drugs

If a manufacturer had a pre-1962 NDA in effect for a drug product, FDA continued its approval if the manufacturer submitted a supplemental new drug application to conform the product's indications for use to those determined to be effective in the DESI review. Yet, as stated above, many drug products had active ingredients and indications that were identical or very similar to the drug products found to be effective in the DESI review but lacked NDA's themselves. In implementing the DESI program with respect to these duplicate products, FDA concluded that each such drug product was a "new drug" that required its own approved NDA before it could be legally marketed (*United States* v. *Generix Drug Corp.*, 460 U.S. 453 (1983)). Additionally, FDA issued a policy statement in the **Federal Register** of May 28, 1968 (33 FR 7758) that revoked the earlier advisory opinions that drugs could be marketed without prior FDA clearance. This rule was codified at 21 CFR 310.100.

Shortly thereafter, FDA created the ANDA procedure for the approval of duplicate products in reliance on the DESI evaluation. In brief, after the DESI program had found a particular drug product to be effective and suitable for ANDA's, FDA published a **Federal Register** notice announcing its conclusions. Any manufacturer of a duplicate drug product that did not have an approved NDA was then required to submit an ANDA to obtain approval to market the duplicate version of the approved drug. (See 34 FR 2673, February 27, 1969; 35 FR 6574, April 24, 1970; and 35 FR 11273, July 14, 1970.)

Before 1984, FDA based these ANDA approvals on the theory that the evidence of effectiveness necessary for approval of an NDA had been provided, reviewed, and accepted during the DESI process. Evidence of the drug's safety had been determined on the basis of information contained in the pioneer NDA and by the subsequent marketing experience with the drug. FDA required ANDA applicants to submit information that showed the applicant's ability to manufacture a product of acceptable quality whose safety and effectiveness were equivalent to the drug product whose safety and effectiveness had been established. Thus, ANDA applicants provided information on the drug product's formulation, manufacture, quality control procedures, and labeling. DESI notices specified additional information, such as bioavailability/bioequivalence data, for the ANDA.

C. Procedures for Duplicates of Post-1962 Drugs ("Paper NDA" Policy)

FDA never extended its ANDA policy for pre-1962 drugs to duplicates of drugs first approved for marketing on or after October 10, 1962, although it did consider the possibility of such an extension either by regulation or through legislation. (See 54 FR 28872 at 28873 and citations therein.) As patents began to expire for many post-1962 drugs, including some high volume, therapeutically important drug products,

many manufacturers became interested in changing the NDA system to permit ANDA's for post-1962 drug products.

FDA did allow some duplicate drug products of drugs first approved after 1962 to be marketed under its "paper NDA" policy. (See 46 FR 27396, May 19, 1981.) This policy permitted FDA to approve NDA's for post-1962 drug products on the basis of safety and effectiveness information derived primarily from published reports based on well-controlled studies. This meant that manufacturers did not have to conduct their own tests, but adequate literature, including detailed reports of adequate and well-controlled studies, was available for only a fraction of the post-1962 drugs. Moreover, the staff effort involved in reviewing paper NDA's ultimately proved to be a substantial and inefficient use of agency resources.

D. The Drug Price Competition and Patent Term Restoration Act of 1984

From 1978 to 1984, Congress considered various bills that would have authorized an ANDA procedure for duplicate versions of post-1962 drug products. Other bills under consideration during this period sought to restore patent life lost while awaiting Federal marketing approval. Congress combined the ANDA procedure for post-1962 drug products and patent term restoration in the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417).

The law consisted of two different titles. Title I authorized the approval of duplicate versions of drug products, approved under section 505 of the act, under an ANDA procedure. Title II authorized the extension of patent terms for approved new drug products (including antibiotics and biological drug products), some medical devices, food additives, and color additives. Congress intended the two titles to provide a careful balance between promoting competition among brand-name and duplicate or "generic" drugs and encouraging research and innovation.

Title I amended section 505 of the act by establishing a statutory ANDA procedure for duplicate and related versions of human drugs approved under section 505(b) of the act. These procedures are inapplicable to antibiotics (which are approved under section 507 of the act) and biological drug products licensed under 42 U.S.C. 262. The statute adopted, with few modifications, the agency's ANDA procedure for pre-1962 drugs. It required all applicants to provide certain patent information; provided for the submission and approval of applications for which the investigations relied on by the applicant to satisfy the "full reports" of safety and effectiveness requirement were not conducted by or for which the applicant had not obtained a right of reference or use from the person who conducted the investigations; established rules for disclosure of safety and effectiveness data submitted as part of an NDA; and provided specific time periods during which ANDA's and NDA's for certain drug products may not be submitted or approved. The act also required FDA to promulgate new regulations implementing the statute. In the **Federal Register** of July 10, 1989 (54 FR 28872), FDA published a proposed rule on ANDA's. This final rule contains must of the provisions contained in that proposal.

FDA published a final rule implementing Title II in the **Federal Register** of March 7, 1988 (53 FR 7298). This rule is codified at 21 CFR Part 60.

II. Highlights of this Final Rule

This final rule amends 21 CFR Part 314 to establish new requirements and procedures for NDA and ANDA applicants under the 1984 amendments. The rule also revises the bioavailability and bioequivalence requirements at 21 CFR part 320 to conform to the 1984 amendments and current agency policy. Minor conforming amendments are made to 21 CFR parts 2, 5, 10, 310, 314, and 433. Additionally, because the agency will issue final regulations governing patent certification and marketing exclusivity requirements at a future date, FDA has revised or deleted cross-references to those provisions and, where possible, replaced them with statutory citations.

The final rule's major provisions are as follows:

A. Abbreviated Applications

The statutory provisions governing ANDA requirements and procedures are at section 505(j) of the act (21 U.S.C. 355(j)).

The statute permits ANDA's for: (1) A drug product that is the "same" as a drug product listed in the approved drug product list published by FDA (the "listed drug") with respect to active ingredient(s), route of administration, dosage form, strength, and conditions of use recommended in the labeling; and (2) a drug product with certain changes from a listed drug if FDA has approved a petition from a prospective applicant permitting the submission of an ANDA for the changed drug product.

Subpart C of part 314 addresses an ANDA applicant's requirements and responsibilities. The final rule is substantially similar to the proposal, although FDA has made some minor changes, such as requiring applicants to include a table of contents in the review copies of an ANDA (21 CFR 314.94(a)(2)), and other minor changes regarding periodic reports from ANDA holders (21 CFR 314.98). One noteworthy change concerns the chemistry, manufacturing, and controls section of an ANDA. Under the proposed rule, applicants would have been required to identify and characterize inactive ingredient differences between their products and those in the reference listed drug. FDA received numerous comments stating that, for many drug products, applicants would be unable to discover which inactive ingredients were used in the reference listed drug. Consequently, the final rule requires applicants to identify and describe such differences regarding inactive ingredients only for topical drug products, drug products intended for parenteral use, and drug products intended for ophthalmic or otic use. The inactive ingredients for these products are listed on the products' labels. For other drug products, the final rule requires applicants to identify and characterize only the inactive ingredients in their own products.

FDA has also revised some policies that were announced in the preamble to the proposed rule. For example, the preamble to the proposed rule indicated that FDA would accept an ANDA submission that contained a bioequivalence protocol. This policy had the unintended effect of encouraging applicants to file incomplete ANDA's. Therefore, FDA is announcing that it will no longer accept an ANDA that does not contain the results of a complete bioequivalence study if such a study is required for approval. These and other changes are described in more detail in the responses to comments below.

B. ANDA Suitability Petitions

Under section 505(j)(2)(C) of the act, an ANDA applicant may petition FDA for permission to file an ANDA for a drug product that has one different active ingredient in a combination product, or whose route of administration, dosage form, or strength differs from that of the listed drug. These are the only types of changes permitted in an ANDA.

The final rule, at 21 CFR 314.93, describes the information that a petitioner must include in its petition. The information must demonstrate that the change from the listed drug requested for the proposed drug product

may be adequately evaluated for approval without data from investigations to show the proposed drug product's safety or effectiveness and that a drug product with a different active ingredient may be adequately evaluated for approval as safe and effective on the basis of information required to be submitted in an ANDA.

In the preamble to the 1989 proposed rule, FDA invited comments on a policy that would provide for the confidentiality of any petition submitted under section 505(j)(2)(C) of the act until FDA either approved or disapproved the petition. At the time of the proposed rule, FDA's policy was to make these petitions available to the public. The agency received an equal number of comments in favor of and opposed to such a policy. The comments favoring confidentiality argued that the public availability of suitability petitions would adversely affect the petitioner's commercial interests. The comments opposing confidentiality said that the public availability of these petitions would enhance the decisionmaking process. FDA agrees with the latter view. By making suitability petitions publicly available, FDA has received valuable comments and information from third parties. These comments and information have contributed to the agency's evaluation of some suitability petitions. Consequently, FDA will continue its policy of making such petitions available to the public.

An ANDA submitted under an approved petition would generally be required to contain the same information as an ANDA for a drug product that is the same as a listed drug except that FDA may require additional information regarding the difference between the proposed drug product and the listed drug. Additionally, FDA requires that the listed drug referred to in the ANDA be the one upon which the petition was based and that the applicant refer to the petition in its ANDA and include a copy of FDA's response approving submission of an ANDA.

C. 505(b)(2) Applications

The 1984 amendments also amended section 505(b) of the act (21 U.S.C. 355(b)) to create another type of application. These applications, known as 505(b)(2) applications, are similar to applications under the agency's "paper NDA" policy. Unlike the paper NDA policy, however, section 505(b)(2) of the act applies to applications that contain investigations relied upon by the applicant to provide full reports of safety and effectiveness where the investigations were not conducted by or for the applicant and the applicant has not obtained a right of reference or use from the person who conducted the investigations. (See 21 U.S.C. 355(j)(2).) Thus, section 505(b)(2) of the act is not restricted to literature-supported NDA's for duplicates of approved drugs; it covers all NDA's for drug products that rely on studies not conducted by or for the applicant or for which the applicant does not have a right of reference.

A 505(b)(2) application is submitted under section 505(b)(1) of the act. Consequently, these applications are subject to the same statutory provisions as full NDA's. The statute, however, gives 505(b)(2) applicants additional obligations, such as patent certification, that are similar to those of ANDA applicants. The final rule addresses 505(b)(2) application procedures at 21 CFR 314.50.

The preamble to the proposed rule (54 FR 28872 at 28891) asked whether FDA should adopt a policy whereby a 505(b)(2) application for a drug product with a change in dosage form, strength, route of administration, or active ingredient would be treated as a petition under section 505(j)(2)(C) of the act. Most comments opposed such a policy, asserting that the policies and procedures for 505(b)(2) applications are or should be distinct from those for suitability petitions. After careful consideration, the agency believes that the policy would prolong review of 505(b)(2) applications and suitability petitions. Consequently, FDA will not adopt the proposed policy.

D. Withdrawal or Suspension of Approval of an ANDA

The statute authorizes the Secretary of Health and Human Services (the Secretary) to withdraw or suspend the approval of any ANDA for a generic drug if: (1) Grounds exist for withdrawal under section 505(e) of the act; (2) the approval of the listed drug referred to by the generic applicant is withdrawn or suspended; or (3) the manufacturer voluntarily withdraws the listed drug from sale for what the agency determines are safety or effectiveness reasons. The final rule contains provisions on withdrawal and suspension at 21 CFR 314.150 to 314.153.

III. Comments on the Proposed Rule

Section 10.30—Citizen Petition

Proposed § 10.30 (e)(2) and (e)(4) would have amended FDA's citizen petition regulations to provide for responses to petitions filed in accordance with section 505(j)(2)(C) of the act.

1. FDA received one comment on proposed § 10.30(e)(2). The comment agreed with the provision, and FDA has finalized it without change.

Section 10.45—Court Review of Final Administrative Action; Exhaustion of Administrative Remedies

2. Two comments objected to proposed § 10.45(d), which would make FDA's response to a petition for reconsideration, rather than a response to a petition under section 505(j)(2)(C) of the act, final agency action. Both comments said that FDA had no authority to require a petition for reconsideration and would give petitioners the right to request a hearing or declare FDA's response to the suitability petition to be final agency action.

FDA disagrees with the comments. FDA has the authority to require adherence to a petition for reconsideration procedure, and such a requirement is practical in this case. From a practical standpoint, the agency receives a large number of suitability petitions each year. If every response to a suitability petition were to be considered as final agency action, the agency would be obliged to devote more resources to each petition to create a comprehensive administrative record. This approach would prolong the review of all suitability petitions without any appreciable benefit to petitioners or the agency. In fact, requiring a petition for reconsideration is to the petitioner's benefit because it ensures that senior FDA officials review the decision on the suitability petition. As for the authority to require a petition for reconsideration, the agency does not agree that it lacks authority to establish by regulation what constitutes final agency action on a petition.

Section 310.305—Records and Reports Concerning Adverse Drug Experiences on Marketed Prescription Drugs for Human Use Without Approved New Drug Applications

3. FDA received one comment on proposed § 310.305 (a)(3) and (c)(4), which, in part, would require persons to report or review reports of therapeutic failure. The proposed rule would amend the existing regulation, which required manufacturers, packers, and distributors of marketed prescription drug products that are not the subject of an approved NDA or ANDA to maintain records and report to FDA "(1) all serious, unexpected adverse drug experiences associated with the use of their drug products and (2) any significant increase in the frequency of a serious, expected

adverse drug experience." The comment suggested that FDA delete "therapeutic failure" and replace it with "significant failure of expected pharmacological action."

The agency declines to adopt the comment's suggestion. Section 310.305 uses the term "therapeutic failure" to correspond to similar language for adverse drug experience reporting for drugs subject to premarket approval. (See § 314.80; 54 FR 28872 at 28911.) In the preamble to the proposed rule, FDA explained that it was deleting the word "significant" from the phrase "any significant failure of expected pharmacological action" because the word "significant" had been a source of confusion and ambiguity. (See 54 FR 28872 at 28889.) Thus, FDA proposed to amend §§ 314.80 and 310.305 to require reports of "therapeutic failure" to eliminate this confusion and require all reports of therapeutic failure (54 FR 28872 at 28889).

Section 314.1—Scope

4. FDA received no comments on the proposed changes to 21 CFR 314.1, but did receive two general comments regarding the proposed rule's scope. One comment asked FDA to permit ANDA's for duplicates of "drug substances for which the specifications are very tightly drawn for both potency and purity," such as insulin preparations, and for copies of biotechnology-derived drug products. The second comment recommended that FDA accept ANDA's with warnings or precautions in addition to those on the reference listed drug's label, provided that such information was not indicative of diminished safety or effectiveness of the generic drug product.

Section 505(j) of the act permits ANDA's only for duplicate and related versions of previously approved drug products. The ANDA applicant relies on a prior agency finding of safety and effectiveness based on the evidence presented in a previously approved new drug application. If investigations on a drug's safety or effectiveness are necessary for approval, an ANDA is not permitted. Thus, under the statute, an ANDA would only be permitted for a drug product with "tight specifications" or a biotechnology-derived drug product only if such a product is the same as a product previously approved under section 505 of the act or if FDA has approved submission of an ANDA under a petition filed under section 505(j)(2)(C) of the act.

As for accepting ANDA's with additional warnings or precautions, section 505 (j)(2)(A)(v) and (j)(3)(G) of the act requires that the applicant's proposed labeling be the same as that of the reference listed drug unless: (1) The labeling differences are due to an approved petition under section 505(j)(2)(C) of the act (otherwise referred to as a "suitability petition"); or (2) the drug product and the reference listed drug are produced or distributed by different manufacturers. (See 21 U.S.C. 355 (j)(2)(A)(v) and (j)(3)(G).) Thus, the exceptions in section 505 (j)(2)(A)(v) and (j)(3)(G) of the act are limited. In addition, under the patent and exclusivity provisions of the act, the ANDA labeling may be required to carry fewer indications than the reference listed product's labeling or to have other labeling differences. In the preamble to the proposed rule, the agency described various types of labeling differences that might fall within the permitted exceptions. An ANDA applicant is required to include in its ANDA a side-by-side comparison of the applicant's proposed labeling with the currently approved labeling for the reference listed drug. The agency will carefully review all differences annotated by the applicant in determining if such differences fall within the limited exceptions permitted by the act.

Section 314.3—Definitions

FDA received 14 comments concerning the definitions of "listed drug" and "reference listed drug" under proposed § 314.3. The proposed rule had defined a "listed drug," in part, as:

> * * * a new drug product that has been approved for safety and effectiveness under section 505(c) or approved under section 505(j) of the act, the approval of which has been withdrawn or suspended under section 505(e) (1) through (5) or (j)(5) of the act, and which has not been withdrawn from sale for what FDA has determined are reasons of safety or effectiveness. Listed drug status is evidenced by the drug product's inclusion in the current edition of FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (the list) or any current supplement to the list.

The proposed rule defined a "reference listed drug" as "the listed drug identified in an abbreviated new drug application or identified by FDA as the drug product upon which an applicant relies in seeking approval of its abbreviated application."

5. With respect to the "listed drug" definition, one comment objected to the exclusion of drugs marketed in compliance with an over-the-counter (OTC) monograph and products with OTC and prescription indications. A second comment said that FDA must list DESI products and post-1962 approved drug products even if the drug products were no longer marketed by September 24, 1984, because section 505(j)(6)(A)(i) of the act requires those products be listed. Four comments objected to listing drugs that have delayed effective dates of approval, while one comment favored listing such drugs.

FDA agrees in part and disagrees in part with the comments. As defined in section 505(j)(6) of the act, a listed drug is one that was approved for safety and effectiveness under section 505(c) of the act or approved under section 505(j) of the act. Drug products marketed in compliance with an OTC monograph rather than pursuant to an approval under section 505(c) or (j) of the act are not listed drugs under the statute.

With respect to DESI products and post-1962 approved drug products that are no longer marketed, FDA stated its position in the preamble to the proposed rule. In brief, FDA declines to allocate its scarce resources to publish and maintain lists of drug products that no longer generate interest with respect to marketing (54 FR 28877 through 28878). FDA does, however, maintain a list of discontinued products as an appendix to the list, and has created a procedure to return these products and other discontinued products to the list where appropriate. If a drug firm wishes to submit an ANDA for a generic version of one of these drug products, it may petition FDA to relist the drug product and provide information to show that the drug product was not withdrawn from sale due to safety or effectiveness reasons.

With respect to drug products with delayed effective dates of approval, FDA has determined that such products should not be listed. An approval with a delayed effective date is tentative and does not become final until the effective date. FDA has concluded that only drug products with final, effective approvals are to be listed under section 505(j)(6) of the act. FDA has amended the definitions of "listed drug" and "the list" to clarify that only drugs with an effective approval are listed drugs.

Similarly, with respect to drug products that are subject to the DESI program and do not meet the conditions for approval of effectiveness as set forth in a DESI notice, FDA has reexamined its policy and no longer regards the DESI notice published in the **Federal Register** as a "listed drug." Section 505(j)(6) of the act describes a "listed drug" as a drug that has been approved for safety and effectiveness. A drug product that must satisfy the conditions for approval of effectiveness as set forth in a DESI notice, therefore, does not fall within section 505(j)(6) of the act and cannot be a listed drug. Therefore, the

agency has revised the definition of listed drug so that a DESI notice will not suffice as a "listed drug."

6. Five comments addressed the definition of "reference listed drug." Three comments suggested that the oldest or first NDA product be the reference listed drug while one comment suggested that any FDA-approved drug be a "referenced listed drug." Another comment recommended designating "reference listed drugs" in the publication titled, "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book."

As noted in the preamble to the proposed rule, FDA intends the reference listed drug to be the same drug product selected by the agency as the reference standard for bioequivalence determinations. Therefore, FDA has revised the definition of "reference listed drug" to make clear that a "reference listed drug" is a listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its abbreviated application. In some instances, such as the submission of an ANDA for a product with multiple strengths, there may be more than one reference listed drug. In these instances, FDA considers each strength to represent a different drug product and will require an ANDA applicant to demonstrate that each proposed drug product is bioequivalent to its corresponding reference listed drug. FDA will identify in future editions of the Orange Book those approved drugs that FDA regards as reference listed drugs. In the interim, FDA will maintain a list of reference listed drugs at the Dockets Management Branch (HFA-305), Food and Drug Administration, room 1-23, 12420 Parklawn Dr., Rockville, MD 20857, until the Orange Book can be revised. FDA hopes that designating a single reference listed drug against which all generic versions must be shown to be bioequivalent will avoid possible significant variations among generic drugs and their brand name counterparts. Such variation could result if generic drugs established bioequivalence to different reference listed drugs.

7. One comment recommended defining "appropriate reliance" for purposes of section 505(b)(2) applications. The comment noted that the preamble to the proposed rule had stated "Appropriate reliance on an analysis of (spontaneous) adverse reaction reports will not cause application to be one described by section 505(b)(2) or 505(c)(3)(D)(of the act." (54 FR 28872 at 28891). The comment said it did not believe that an application containing an analysis of adverse reaction reports in place of safety studies "should be considered a full application for the purpose of 'breaking exclusivity' granted to another sponsor's drug."

FDA believes that the comment has misinterpreted the agency's position. The preamble to the proposed rule stated that, for drug products with a U.S. marketing history, an analysis of the spontaneous adverse reaction reports "may, in some cases, be substituted for some of the safety data" in a full NDA (54 FR 28872 at 28891). The agency believes that an analysis of spontaneous adverse reaction can provide some safety information when: (1) The drug product has a U.S. marketing history; and (2) there is a substantial amount of adverse drug reaction experience for that drug product. For example, an applicant could submit such an analysis to substitute for certain animal studies that would otherwise be required to show the kinds of risks that might be expected when the drug is tested in humans, or to show which certain, infrequent side effects occur rather than conduct large, Phase 3 clinical studies to prove the same result. Thus, FDA does not contemplate that an applicant under section 505(b)(1) of the act will substitute an analysis of adverse reaction reports for all safety information.

Section 314.50—Content and Format of an Application

The proposed rule contained several revisions and additions to the existing requirements at 21 CFR 314.50. The proposed revisions were minor. For example, under proposed § 314.50(a)(2), an applicant would be required to provide a statement whether the submission is an original application, a 505(b)(2) application, a resubmission, or a supplement to an application. The proposed additions focused on patent information and certifications and claimed exclusivity, and are not included in this final rule.

8. Proposed § 314.50(g)(3) would require an applicant who is submitting an application under section 505(b) of the act and who has a "right of reference or use" as defined in § 314.4(b) to include a "written statement signed by the owner of the data from each such investigation that the applicant may rely on in support of the approval of its application, and provide FDA access to, the underlying raw data that provide the basis for the report of the investigation submitted in its application." One comment would provide FDA access to the underlying raw data "only if FDA would not otherwise have access to the information that is needed for an adequate review of the application."

Section 314.50(g)(3) simplifies the process in which FDA can have access to raw data if such data are needed to review an application. Without this provision, if FDA determined that it needed to examine the raw data, it would be obligated to suspend the review process, request that the applicant obtain a written statement from the owner of the data to give FDA access to the data, and wait for the written statement to arrive before continuing its review. The provision, therefore, streamlines the review process by eliminating the need for requests and correspondence between FDA, applicants, and owners of data referenced by applicants after FDA had begun its review. The agency will utilize this authority when it believes that access to the raw data is necessary for reviewing the application.

Section 314.54—Procedure for Submission of an Application Requiring Investigations for Approval of a New Indication for, or Other Change from, a Listed Drug

FDA received two comments on proposed § 314.54. This provision would permit any person seeking approval of a drug product that represents a modification of a listed drug and for which investigations other than bioequivalence or bioavailability studies are essential to the approval of the change to submit a 505(b)(2) application.

9. One comment said FDA should revise proposed § 314.54(a) to state that a 505(b)(2) application is appropriate for changing a drug from prescription to OTC status.

FDA declines to adopt the comment. The regulation, as written, does not preclude submission of a 505(b)(2) application to change a drug from prescription to OTC status, so the suggested revision is unnecessary.

10. A second comment objected to proposed § 314.54(b) because it would prevent applicants from submitting applications requiring investigations for approval of a change from a listed drug for drugs whose only difference from the reference listed drug is that the extent to which the listed ingredients are absorbed or otherwise made available to the site of action to a lesser degree compared to the reference listed drug. The comment said FDA should judge drug products individually.

FDA declines to accept the comment. Differences in the extent to which a drug is absorbed will affect the drug's

therapeutic effectiveness. For example, a drug whose extent of absorption is less than that of the reference listed drug may be less effective or even ineffective. Consequently, FDA will not accept applications for products under § 314.54(b) whose extent of absorption is less than that for the reference listed drug.

FDA has, however, amended § 314.54(b) to state that it also will not accept an application under § 314.54 for a product whose only difference from the reference listed drug is an unintentional, lesser rate of absorption. FDA is making this change because a drug whose rate of absorption is unintentionally less than that of the reference listed drug may be less effective.

Section 314.55—Abbreviated Application; Section 314.56—Drug Products for Which Abbreviated Applications are Suitable

FDA received no comments on its proposal to remove these provisions, and, therefore, has removed them from 21 CFR part 314.

Section 314.60—Amendments to an Unapproved Application

11. FDA received two comments on proposed § 314.60. In general, proposed § 314.60 stated when an applicant could submit an amendment to an application filed under § 314.100 but not yet approved, and also stated when an unapproved application could not be amended. One comment asked FDA to explain how exclusivity would be affected if a section 505(b)(2) application is amended before another section 505(b)(2) application, which had been filed earlier, is approved. The second comment claimed that § 314.60(d) would permit section 505(b)(2) applications to become effective regardless of new drug exclusivity. This comment said FDA should revise the rule to declare that a section 505(b)(2) application "that would not be approvable but for a previously approved application * * * be made subject to the exclusivity of that previously approved application."

The preamble to the proposed rule explained that, for concurrently pending 505(b)(2) applications, any 505(b)(2) application submitted to FDA before the approval of another NDA that qualifies for exclusivity under section 505(c)(3)(D)(ii) of the act (granting 5 years of exclusivity) is "not affected by this exclusivity provision." (54 FR 28872 at 28901.) This is because section 505(c)(3)(D)(ii) of the act prohibits only the "submission," and not the approval, of a 505(b)(2) application that refers to a previously approved application. The only exception to the policy on concurrently pending 505(b)(2) applications is where "the first applicant to obtain approval and to qualify for exclusivity publishes its data and the competing applicant amends its application to include the first applicant's published data * * *. Where that data would be essential to the approval of the competing application, the second application will be deemed to refer to the first application" and not permitted to avoid exclusivity. Id. This policy is covered under § 314.60(b)(1)(ii), so the comment's suggestion is unnecessary.

FDA disagrees with the second comment's assertion that the rule permits section 505(b)(2) applications to become effective regardless of exclusivity. The statute clearly states that the Secretary may not approve, or, in one case, that applicants cannot submit, an application before an exclusivity period expires. (See 21 U.S.C. 355(c)(3)(D)(i) through (c)(3)(D)(v).) The rule observes these restrictions and pertains only to amendments to unapproved applications; it does not address approvals. Section 314.60(b) is, in fact, designed to protect an applicant's exclusivity under section 505(c)(3)(D)(ii) of the act while simultaneously preserving an applicant's incentive to publish the studies on which approval was based. Thus, FDA does not adopt the comment's suggested language.

Section 314.70—Supplements and Other Changes to an Approved Application

FDA received no comments on this provision, but has amended the provision to adopt references to statutory, rather than regulatory, provisions or to explain what information should be provided. However, the agency wishes to remind ANDA applicants that, as noted in paragraph 4 above, the labeling for an ANDA product must, with few exceptions, correspond to that for the reference listed drug.

Section 314.71—Procedures for Submission of a Supplement to an Approved Application

FDA received no comments on this provision and has finalized it without change.

Section 314.80—Postmarketing Reporting of Adverse Drug Experiences

FDA proposed several changes to 21 CFR 314.80 under the proposed rule. Section 314.80(a) under the existing regulation defined an "adverse drug experience," in part, as "any significant failure of expected pharmacological action." The proposed rule would delete the adjective "significant" from this definition and, as a result, require reporting of "any failure of expected pharmacological action." The proposed rule also would require applicants to review all adverse drug experience information "obtained or otherwise received by the application from any source, foreign or domestic," and to review periodically the frequency of reports of adverse drug experiences "that are both serious and expected and reports of therapeutic failure (lack of effect), regardless of source, and report any significant increase in frequency as soon as possible * * *."

12. FDA received several comments on adverse drug experience reporting under proposed § 314.80. Four comments supported the rule. Five objected to deleting the adjective "significant" from the phrase "any significant failure of expected pharmacological action" in the existing definition of "adverse drug experience," or asked FDA to limit the rule. The comments said the rule would require additional reports and generate reports with little value.

As stated in the preamble to the proposed rule, FDA deleted the word "significant" from § 314.80 because the word has been a source of confusion and ambiguity (54 FR 28872 at 28889). By amending the rule, FDA intended to require reports of any drug failure, as the agency considers all such failures to be significant. Id. This modification will provide a complete picture of adverse drug experiences, rather than selected reports, and will improve the agency's ability to determine whether it should take regulatory action.

13. One comment said a "therapeutic failure" should include excessive or exaggerated responses to a drug.

FDA declines to amend the rule as suggested. FDA does not consider such responses to be "therapeutic failures" under § 314.80. They are, however, covered under § 314.80 because they usually manifest themselves as adverse drug experiences. Consequently, applicants are obligated to report them as adverse drug experiences.

Section 314.81—Other Postmarketing Reports

The proposed rule would amend 21 CFR 314.81 to require applicants to submit a Form FDA 2657 (Drug Product Listing) within 15 working days of the withdrawal from sale of a drug product. The proposed rule also contained details regarding the information to be submitted, such as the National Drug Code number, the drug product's

established name and proprietary name, and the date of withdrawal from sale.

14. One comment asked FDA to clarify whether an applicant's obligation to submit postmarketing reports begins when FDA approves its ANDA or when the ANDA approval becomes effective.

Although the preamble to the proposed rule said proposed § 314.81 would apply upon ANDA approval regardless of the ANDA's effective date (54 FR 28872 at 28889), FDA has reconsidered this position in light of its policy on delayed effective dates and approvals. FDA does not consider a drug to be approved until the effective date of approval and regards those drug products with delayed effective dates as having tentative approvals. This policy affects § 314.81 because section 505(k) of the act authorizes reporting requirements for drug products that have an approval "in effect." Thus, an applicant's obligation to submit postmarketing reports will begin when the ANDA approval becomes effective.

15. Two comments addressed the 15-day reporting deadline in proposed § 314.81(b)(3)(iii)(*a*). One comment said a company "does not always know within 15 days of its last shipment that it intends to discontinue marketing a product" and "it is not always clear to a company whether a product is going to be withdrawn from marketing or just temporarily suspended." The comment would have applicants notify FDA that they will withdraw a product when they decide to permanently withdraw the product from sale. The second comment added that the existing rule's annual reporting requirement was satisfactory.

FDA believes the first comment misinterprets the provision. FDA does not expect parties to submit reports within 15 days from the date of their last shipment. The 15-day period begins from the time the firm decides to withdraw the product from the market. Such withdrawals are not limited to permanent withdrawals; FDA is interested in any decision to discontinue marketing because of the possible implications for the product's safety and efficacy. The agency also declines to replace the 15-day reporting period with an annual reporting requirement as suggested by the second comment. The withdrawal of an approved NDA drug product may affect the marketing of duplicate ANDA drug products, so timely reports of drug product withdrawals may be very important.

Section 314.92—Drug Products for Which Abbreviated Applications May be Submitted

FDA received four comments on proposed § 314.92. The proposed rule stated that abbreviated applications are suitable for certain drug products, such as drug products that are the same as a listed drug, drug products that meet the monograph for an antibiotic drug for which FDA has approved an application, drug products for which FDA has found an ANDA to be suitable and has announced such a finding in the **Federal Register**, and drug products that FDA has declared to be suitable for an ANDA submission under the petition procedures.

16. One comment asked FDA to refuse ANDA's for DESI drugs on the grounds that the statute only applies to post-1984 ANDA's. The comment noted that DESI drugs are reviewed by category rather than active ingredient and said some DESI active ingredient categories lack a "readily identifiable pioneer NDA product." Another comment supported ANDA's for DESI drugs.

The ANDA provisions of the 1984 amendments are applicable to all generic drugs for which approval is sought after September 24, 1984, the date on which the statute was enacted. Perpetuating different ANDA systems for pre-1962 drugs and post-1962 drugs would be needlessly confusing, illogical, and inefficient to FDA, the public, and industry. Therefore, FDA has included DESI drugs in these regulations.

Upon further consideration, FDA agrees that ANDA's may be inappropriate for some DESI drug products. In the DESI process, a DESI-reviewed NDA or ANDA is usually considered approved for safety and effectiveness through the approval of a supplement that brings the NDA or ANDA drug product into compliance with a DESI-upgrade notice. The DESI-upgrade notice describes what information the NDA or ANDA holder must provide in order for its drug product to be considered effective. If the NDA or ANDA holder complies with the notice through an approved supplement, then the drug product is considered to be safe and effective and can be listed in the Orange Book. Once this occurs, a person may be able to submit an ANDA for the product. However, if the NDA or ANDA holder fails to comply with the notice, the NDA or ANDA drug product is not considered to be approved for effectiveness and cannot be a listed drug. Under these circumstances, an ANDA cannot be submitted because there is no "listed drug." Therefore, FDA has revised § 314.92 by removing paragraph (a)(3) and renumbering paragraph (a)(4) as (a)(3). An applicant seeking to rely on the findings reflected in a DESI-upgrade notice, in the absence of a listed drug, should submit its application under section 505(b)(2) of the act.

Once a drug subject to a DESI notice is approved for safety and effectiveness and can serve as a listed drug, the agency will require the submission of an ANDA under section 505(j) of the act for a generic version of the product. As a matter of policy, the agency does not accept applications under section 505(b)(2) of the act when there is a listed drug that would provide a basis for an application under section 505(j) of the act. For clarity, FDA has added a new paragraph (d)(9) in § 314.101. The issue had been discussed in the preamble to the proposed rule (54 FR 28890 through 28891). At that time, the agency proposed to treat a 505(b)(2) application as submitted under section 505(j) of the act if the application was for a duplicate of a listed drug eligible for approval under section 505(j) of the act. Id. FDA believes that the policy it is describing in new § 314.101(d)(9), that an application for a drug such as this needs to be submitted by the applicant as an ANDA under section 505(j) of the act, is the preferable approach.

17. Two comments concerned proposed § 314.92(a)(1), which said, in part, that an ANDA would be suitable for a drug product that is the same as a listed drug and that the term "same as" means "identical in active ingredient(s), dosage form, strength, route of administration, and conditions of use, except that conditions of use for which approval cannot be granted because of exclusivity or an existing patent may be omitted." The proposed rule would also require potential applicants to comply with § 314.122, "Submitting an abbreviated application for, or a 505(j)(2)(C) petition that relies on, a listed drug that is no longer marketed," if the listed drug had been voluntarily withdrawn or not offered for sale by its manufacturer. One comment asked FDA to define "strength." The second objected to the language on voluntary withdrawals. The comment said NDA holders should disclose the reasons for withdrawing a product, and FDA should determine whether those reasons raise safety or efficacy questions, and then give ANDA holders an opportunity to examine and respond to the information on the withdrawal.

"Strength" refers to the amount of the product's active ingredient and is usually expressed in terms of weight. For example, a drug that is available as a 50 milligram (mg) tablet and a 100 mg tablet has two "strengths."

As for voluntary withdrawals and the reasons for a withdrawal, FDA refers

the reader to its discussion of identical comments at § 314.161 below.

17a. Additionally, although the preamble to the proposed regulation stated: "Section 507(a) of the act permits the submission of abbreviated applications for *duplicates* of all antibiotics the agency has already approved for marketing" (emphasis added) (54 FR 28872 at 28878), the proposed regulation (§ 314.92(a)(2)) referred only to products that meet the monograph. Because, in some instances, a generic antibiotic may be a duplicate of an approved antibiotic but may not meet the monograph in every respect for that approved antibiotic, the agency has broadened the language of the proposed regulation to include generic antibiotics that either are duplicates of, or meet the monograph for, the approved antibiotic. This change is made at the agency's initiative to reflect the intent of the agency expressed in the preamble to the proposed regulation.

Section 314.93—Petition To Request a Change from a Listed Drug

Proposed § 314.93(b) stated that a person who wants to submit an ANDA for a drug product "which is not identical to a listed drug product in route of administration, dosage form, and strength, or in which one active ingredient is substituted for one of the active ingredients in a listed combination drug, must first obtain permission from FDA to submit such an abbreviated application."

18. Most comments agreed with the proposal, but one comment suggested that the rule be revised to state that FDA will not accept a suitability petition if the proposed drug product has different inactive ingredients which "may have some effect on the safety or efficacy of the altered product." Another comment asserted that the safety and effectiveness of a proposed new combination drug cannot be determined without drug interaction data.

FDA declines to accept the comments. Under the statute, suitability petitions are for drugs that have a different active ingredient, route of administration, dosage form, or strength. (See 21 U.S.C. 355(j)(2)(C).) A person seeking marketing approval of a drug product that differs from the listed drug product only with respect to inactive ingredients is not required to submit a suitability petition. FDA also notes that § 314.94(a)(9)(ii) requires applicants to identify and characterize the inactive ingredients used in the proposed drug product, and this information should permit FDA to determine whether the different inactive ingredients affect the product's safety. If FDA determines that the inactive ingredients of the drug are unsafe, the agency will refuse to approve the ANDA. (See 21 U.S.C. 355(j)(3)(H); 21 CFR 314.127.)

As for proposed new combination drug products, the statute expressly authorizes petitions for drugs with one different active ingredient. The petitioner must provide information to show that the different active ingredient is "an active ingredient of a listed drug or a drug which does not meet the requirements of section 201(p)" (21 U.S.C. 355(j)(3)(C)(iii)(II)). Although the statute does not expressly require drug interaction data, it authorizes FDA to refuse to approve a petition if "investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients" or if a drug product containing a different active ingredient "may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application" (21 U.S.C. 355 (j)(2)(C)(i) and (j)(2)(C)(ii)). Thus, if the agency determines that the safety and effectiveness of a proposed combination drug product cannot be shown without drug interaction data, FDA will not approve the petition. FDA has, on its own initiative, revised the language in § 314.93(d) to clarify the circumstances under which a petitioner may identify more than one listed drug. The revised language corresponds more closely to the statutory language.

19. One comment suggested that the agency revise proposed § 314.93(d)(3) regarding proposed combination drug products with one different active ingredient. The proposed rule would require petitioners to provide information to show that:

> If the proposed drug product is a combination product with one different active ingredient, including a different ester or salt, from the reference listed drug, that the different active ingredient has previously been approved in a listed drug or is a drug that does not meet the definition of "new drug" in section 201(p) of the act.

The comment suggested that § 314.93(d)(3) be revised to state that ingredients listed as Category I (generally recognized as safe or generally recognized as effective) in a tentative final or final OTC monograph are "substitutable ingredients."

FDA declines to revise the rule as requested. The rule is consistent with section 505(j)(2)(A)(ii)(III) of the act, which states that the different active ingredient must be "an active ingredient of a listed drug or of a drug which does not meet the requirements of section 201(p) * * *." Therefore, in order to be a "substitutable ingredient," a Category I ingredient must be either an active ingredient of a listed drug or an active ingredient that does not meet the definition of a "new drug." An ingredient included in a final OTC drug monograph would be a "substitutable ingredient" because it does not meet the definition of a "new drug."

20. One comment asked FDA to accept petitions to submit an ANDA for a product whose labeling differs from the reference listed drug by being "more clear or offer better directions regarding how the drug should be taken."

FDA declines to accept the comment. Suitability petitions are for drugs that have a different active ingredient, route of administration, dosage form, or strength. (See 21 U.S.C. 355(j)(2)(C).) Labeling differences, therefore, are not proper subjects for a suitability petition.

FDA reminds applicants that the labeling for an ANDA product must be the same as the labeling for the listed drug product except for differences due to different manufacturers, exclusivity, etc. (See 21 U.S.C. 355(j)(3)(G).) An ANDA applicant who believes that the labeling for a proposed drug product should differ from that approved for the reference listed drug should contact FDA to discuss whether labeling for both generic and listed drugs should be revised.

21. One comment objected to proposed § 314.93(e)(1)(v) because FDA would refuse to approve a petition if the reference listed drug had been voluntarily withdrawn from sale and FDA had not determined whether the withdrawal was for safety or effectiveness reasons. The comment would revise the rule to require manufacturers to provide detailed reasons for withdrawing a drug product and, if FDA concluded that those reasons involved safety or effectiveness issues, require FDA to provide this information to prospective ANDA applicants or petitioners.

FDA declines to amend the rule as requested. The statute does not require FDA to determine why a listed drug was withdrawn from sale in every case, and the agency believes it would be impractical to do so. The agency discusses this subject in greater detail in its discussion of the comments to 21 CFR 314.151 through 314.152.

22. Five comments focused on the term "limited confirmatory testing" mentioned in the preamble to proposed § 314.93(e)(2). Proposed § 314.93(e)(2) stated that the phrase, "investigations must be conducted," meant "information derived from animal or clinical studies is necessary to show that the drug product is safe or effective." The

preamble to the proposed rule explained that:

> If preclinical or clinical data are needed to support safety, or if clinical data are needed to support the effectiveness of the requested change, then an abbreviated new drug application is not appropriate for the proposed drug product, and FDA will not approve a petition. However, under certain circumstances, data from limited confirmatory testing to show that the characteristics that make the proposed drug product different from the listed drug do not alter its safety and effectiveness may be accepted in a petition or as additional data to be included in an ANDA resulting from an approved petition.

54 FR 28872 at 28880.

One comment asked FDA to define "limited confirmatory testing." Two comments noted that the preamble to the proposed rule would permit limited confirmatory testing but that the rule itself would not approve a petition if animal or clinical studies are needed. The comments suggested revising the rule so a drug product "for which any testing other than bioavailability testing is required is ineligible for ANDA treatment." Two other comments said limited confirmatory testing would create a new class of applications or permit firms to avoid full NDA requirements; these comments would eliminate such testing or limit their use to "very rare circumstances."

As stated in the preamble to the proposed rule, by "limited confirmatory testing," FDA means "simple studies intended to rule out unlikely problems." (See 54 FR 28872 at 28880.) Such tests do not include animal or clinical studies whose information is necessary to show that the drug is safe or effective. (See 21 CFR 314.93(e)(2).) Thus, FDA does not intend to permit petitioners to substitute limited confirmatory testing for clinical studies or otherwise circumvent NDA requirements.

23. One comment objected to the language in proposed § 314.93(e)(3), which said FDA may "at any time during the course of its review of an abbreviated new drug application, request additional information required to evaluate the change approved under the petition." The comment argued that this language would permit FDA to revoke its approval of a petition even after an ANDA is submitted.

When read in its entirety, § 314.93(e)(3) states that when FDA approves a petition, the agency may describe what additional information, if any, will be required to support an ANDA for the drug product, and that this approval should not be construed as preventing FDA from requesting additional information to evaluate the ANDA. Thus, the provision concerns information needed to support approval of the ANDA rather than the information needed to evaluate the petition.

As for "revoking" approval of a suitability petition, FDA is amending § 314.93 by adding a new paragraph (f) to give the agency express authority to withdraw approval of a suitability petition if new information indicates that approval should be withdrawn. Such information can come from any source, including ANDA's submitted under the petition. This amendment will ensure that suitability petition approvals continue to reflect valid, scientific judgment and reasoning and prevent would-be ANDA applicants from relying on suitability petitions that, in light of new information, would not have been granted had the new information been available when the petition was under consideration.

Section 314.94—Content and Format of an Abbreviated Application

FDA received over 100 comments pertaining to ANDA format and content. Most recommended revisions or clarification while several expressed general agreement with specific provisions.

Table of Contents

24. One comment suggested that proposed § 314.94(a)(2), which would require the archival copy of an ANDA to contain a table of contents, be revised to require that both archival and review copies of an ANDA contain a table of contents.

Although the provision in question only pertains to archival copies of an application, FDA agrees with the comment and has amended § 314.94(d)(2) accordingly.

Basis for an ANDA Submission

25. Two comments addressed reference listed drugs under proposed § 314.94(a)(3)(i). The proposed rule would require an ANDA to contain "the name of the reference listed drug, including its dosage form and strength." The comments noted that the preamble to the proposed rule stated that the pioneer drug would "usually" be the reference listed drug, but, if more than one listed drug existed for the same drug product, the preamble recommended that applicants contact the Director of the Division of Bioequivalence before selecting a reference listed drug (54 FR 28880–28881). The comments asked FDA to explain how FDA determines which drugs should be reference listed drugs, and one comment proposed that the pioneer drug serve as the reference listed drug "unless there are sound scientific reasons for which a substitute may be preferred."

As stated above, FDA has revised the rule so that FDA will designate all reference listed drugs. Generally, the reference listed drug will be the NDA drug product for a single source drug product. For multiple source NDA drug products or multiple source drug products without an NDA, the reference listed drug generally will be the market leader as determined by FDA on the basis of commercial data. FDA recognizes that, for multiple source products, a product not designated as the listed drug and not shown bioequivalent to the listed drug may be shielded from direct generic competition. If an applicant believes that there are sound reasons for designating another drug as a reference listed drug, it should consult FDA. Once FDA designates that reference listed drug, that drug will continue to be the reference standard even if the drug is later replaced as the market leader. The Orange Book will identify all reference listed drugs, so applicants are no longer instructed to call the Director of the Division of Bioequivalence. FDA has, however, deleted the language regarding **Federal Register** notices from § 314.94(a)(3)(i). As discussed elsewhere in this rule, the agency no longer regards a DESI notice as a listed drug and will not accept an ANDA in the absence of a listed drug.

Active Ingredients

26. Two comments sought more exacting standards or requirements for establishing that a generic drug and a listed drug contain the "same" active ingredients. Proposed § 314.94(a)(5)(i) would require an ANDA to contain information to show that the active ingredient in a single-active-ingredient product to be "the same as that of the reference single-active-ingredient listed drug." One comment stated that the active ingredients in the proposed drug product must be identical to those in the reference listed drug and that blood level comparisons are inadequate to establish such identity. The comment added that the rule should provide technical or scientific criteria for determining whether two active ingredients are equivalent.

The second comment would require applicants to demonstrate that their active ingredients "exhibit the same physical and chemical characteristics, that no additional residues or impurities can result from the different manufacture or synthesis process; and that the stereochemistry characteristics

and solid state forms of the drug have not been altered."

Under the statute, an ANDA applicant must show that its active ingredient is the same as that in the reference listed drug (21 U.S.C. 355(j)(2)(A)(ii)). FDA will consider an active ingredient to be the same as that of the reference listed drug if it meets the same standards for identity. In most cases, these standards are described in the U.S. Pharmacopeia (U.S.P.). However, in some cases, FDA may prescribe additional standards that are material to the ingredient's sameness. For example, for some drug products, standards for crystalline structure or stereoisomeric mixture may be required. Should questions arise, an applicant should contact the Office of Generic Drugs to determine what information would be necessary to demonstrate that its active ingredient is the same as that in the reference listed drug.

As for possible impurities or residues in the ANDA product, ANDA applicants would be required to provide information on the drug substance and the drug product as part of the chemistry, manufacturing, and controls section of the application. (See 21 CFR 314.94(a)(9); 314.50(d)(1).) This would include information on impurities and residues. The "Guideline for Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances" suggests that impurities "should not only be detected and quantitated, but should also be identified and characterized when this is possible with reasonable effort." This guideline adds that "All major impurities should be individually limited. The maximum amount per unit dose of every individual impurity should be provided. If there is information on toxicity or information on toxic limits that have been set of these impurities, this information should be provided." If the manufacturing, packing, or processing controls cannot ensure the product's identity, strength, quality, and purity, or if the drug's composition is unsafe, FDA will not approve the ANDA. (See 21 U.S.C. 355 (j)(3)(A) and (j)(3)(H).)

27. One comment sought clarification of proposed § 314.94(a)(5)(ii)(A). That provision would require an ANDA for a combination drug product to contain information to show that the active ingredients are the same as those for the reference listed drug, or,

> * * * if one of the active ingredients differs from one of the active ingredients of the reference listed drug and the abbreviated application is submitted pursuant to the approval of a petition under § 314.93 to vary such active ingredient, information to show that the other active ingredients of the drug product are the same as the other active ingredients of the reference listed drug, information to show that the different active ingredient of another listed drug or of a drug which does not meet the definition of a "new drug" in section 201(p) of the act, and such other information about the difference active ingredient that FDA may require.

The comment asked FDA to clarify the phrase "such other information about the different active ingredient that FDA may require."

The phrase quoted by the comment reflects the statutory language at section 505(j)(2)(A)(ii)(III) of the Act. FDA has not requested any additional information from applicants under this authority, and cannot predict what type of information it would require. Nevertheless, the final rule keeps this language and will not foreclose its use.

Bioequivalence

FDA received nine comments on proposed § 314.94(a)(7). That section describes the kinds of information required to demonstrate bioequivalence.

28. One comment suggested that applicants be given the option of submitting a proposed bioavailability or bioequivalence study protocol for review and comment either as part of an ANDA or before submitting an ANDA so that applicants do not conduct questionable or unnecessary studies.

Since publication of the proposed rule, FDA has changed its policies regarding the submission of incomplete ANDA's. Under earlier policy, FDA permitted ANDA applicants to submit ANDA's with bioequivalence study protocols and to provide bioequivalence study data at a later date. This policy has resulted in a significant and unwarranted expenditure of resources in reviewing applications that had little potential for approval. FDA will therefore no longer accept an ANDA that does not contain complete bioequivalence study data if such data are required for approval. However, with respect to pre-ANDA submissions of bioequivalence protocols, FDA will continue, to the extent that time constraints and resources permit, to provide guidance on such protocols before an ANDA is submitted. Applicants wishing such guidance may submit requests for review of proposed protocols to the Director, Division of Bioequivalence. The Division will attempt to provide informal comments on such submissions as time and resources permit. The agency has also revised § 314.94(a)(7)(i) to delete the language concerning **Federal Register** notices. As stated earlier, the agency no longer regards a DESI notice as a listed drug and will not accept an ANDA in the absence of a listed drug.

29. One comment recommended that FDA give each holder of an NDA for an innovator drug an opportunity to comment on any bioequivalence study protocol proposed by an ANDA applicant if "nonabsorbed drugs" are involved. The comment would also establish deadlines for the NDA holder to respond to the protocol and for FDA to issue a decision.

FDA has considerable scientific expertise in the critical review of bioequivalence protocols. If additional expertise is necessary, the agency will seek advice from sources such as the Generic Drug Advisory Committee on an "as needed" basis. The agency also notes that, as a basic matter, giving NDA holders a role in reviewing the applications of potential competitors could create a conflict of interest and compromise an applicant's confidential information. Therefore, FDA is not adopting the comment.

30. One comment stated that an FDA request for additional information under proposed § 314.94(a)(7)(ii) should be made within 30 days after the initial submission of the ANDA. As drafted, proposed § 314.94(a)(7)(ii) would require an ANDA submitted under a suitability petition to vary an active ingredient to contain "the results of any bioavailability or bioequivalence testing required by the agency, and any other information required by the agency to show that the different active ingredient is of the same pharmacological or therapeutic class as that of the changed ingredient in the reference listed drug, and that the proposed drug product can be expected to have the same therapeutic effect as the reference listed drug."

FDA declines to accept the comment. If FDA determines, after receiving an ANDA that was submitted pursuant to an approved suitability petition, that the ANDA applicant must submit additional information, this determination represents a finding that the information is necessary to ensure that the proposed ANDA drug product has the same therapeutic effect as the reference listed drug. (See 21 U.S.C. 355(j)(2)(A)(iv).) The agency will not, therefore, forego requesting such information simply because a specific time period has expired. FDA will act on ANDA's as expeditiously as agency resources and priorities permit, but cannot guarantee that the agency will be able to identify, within 30 days, all instances where it needs to request information.

31. One comment interpreted proposed § 314.94(a)(7)(ii) to mean that

safety and efficacy studies could be required and asked FDA to state that a product requiring more than bioequivalence testing cannot be the subject of an ANDA.

FDA will not require safety and effectiveness investigations under § 314.94(a)(7)(ii). As stated in section 505(j)(2)(C) of the act and § 314.93(e)(1)(i), if clinical investigations are needed to establish a product's safety or effectiveness, that product is not suitable for approval under an ANDA. FDA does not, however, interpret this section to preclude the use of data to demonstrate whether a proposed drug product will have the same therapeutic effect as a reference listed drug.

FDA has, however, revised § 314.94(a)(7)(ii) to state that an ANDA submitted under an approved petition must contain the results of any bioavailability or bioequivalence testing or any other information required by FDA to show that the active ingredients of the proposed drug product are of the same pharmacological or therapeutic class as those in the reference listed drug and that the proposed drug product can be expected to have the same therapeutic effect as the reference listed drug. This change encompasses ANDA's for single-ingredient drug products submitted pursuant to an approved suitability petition. The proposed rule inadvertently omitted a reference to such ANDA's and unintentionally created a potential problem for some ANDA applicants. For example, if the approved suitability petition permitted a change in dosage form, it might be difficult for some applicants to demonstrate bioequivalence between the new dosage form and the dosage form of the reference listed drug, e.g., between a cream and a tablet. The change corrects this problem and corresponds to the statutory language in section 505(j)(2)(A)(iv) of the act.

32. Proposed § 314.94(a)(7)(ii)(A) stated that FDA would consider a proposed drug product to have the same therapeutic effect as a reference listed drug if the applicant provided information demonstrating that:

> There is an adequate scientific basis for determining that substitution of the specific proposed dose of the different active ingredient for the dose of the member of the same pharmacological or therapeutic class in the reference listed drug will yield a resulting drug product of the same safety and effectiveness.

One comment would delete the adjective "same" from the phrase "of the same safety and effectiveness" because "[i]t may not be possible to have exactly the same safety and effectiveness, for example, if a different active ingredient is included in a combination product and safety or efficacy is enhanced." The comment recommended replacing the words "of the same safety and effectiveness" with "whose safety and effectiveness have not been adversely affected."

FDA agrees and has revised the rule accordingly.

33. One comment suggested amending proposed § 314.94(a)(7)(iii) to state that waivers from the in vivo bioavailability or bioequivalence requirement are possible under 21 CFR 320.22. As drafted, proposed § 314.94(a)(7)(iii) made no reference to waivers.

FDA declines to adopt the suggestion. Section 314.94(a)(7), generally, and § 314.94(a)(7)(iii), specifically, do not require in vivo bioequivalence. The provisions state the statutory requirement that an ANDA contain information to show bioequivalence and that, if that information is obtained from an in vivo study, the applicant include in its application information about the analytical and statistical methods used and information to show that the study was conducted in compliance with 21 CFR parts 50 and 56. Information to show bioequivalence may, depending on the drug product, come from an in vivo or an in vitro study.

34. Two comments focused on institutional review board (IRB) and informed consent requirements at proposed § 314.94(a)(7)(iii). The proposed rule would have required a statement regarding compliance with the IRB and informed consent requirements at 21 CFR parts 56 and 50, respectively, for each in vivo bioequivalence study in an ANDA. One comment asked FDA to identify the party responsible for providing a statement on IRB review and informed consent. The comment suggested that the "sponsor," which FDA presumes is the ANDA applicant, make such statements only after the sponsor had conducted an "appropriate on-site inspection of the records and the informed consent process as the study is performed." The second comment suggested revising the regulation to identify the party making the statement. The comment explained that sponsors who have transferred their obligations to contract research organizations should be able to provide the names and addresses of such organizations rather than make the statements on IRB review and informed consent themselves.

FDA declines to accept the comments. The ANDA applicant is ultimately responsible for ensuring that the ANDA satisfies all statutory and regulatory obligations, including IRB review under 21 CFR part 56 and informed consent under 21 CFR part 50. This is true even if the ANDA applicant has elected to use a contract research organization to conduct the study. If an ANDA does not contain such a statement, FDA may refuse to receive it. (See § 314.101(b)(3); see also § 314.101(d)(7).)

Labeling

Proposed § 314.94(a)(8) set forth labeling requirements for ANDA's. The proposal would require applicants to provide copies of the currently approved labeling for the reference listed drug, labels and labeling for the proposed drug product, and a statement that the applicant's proposed labeling is the same as that for the reference listed drug except for certain differences, including, but not limited to, differences due to exclusivity or patent protection. The proposal, at § 314.94(a)(8)(iv), would also require applicants to provide a side-by-side comparison of the applicant's proposed labeling with the approved labeling for the reference listed drug. The proposed rule did not state how applicants could acquire copies of the reference listed drug's labeling, but the preamble said current approved labeling could be obtained under the Freedom of Information Act (FOIA) (54 FR 28872 at 28884).

35. Several comments stated that obtaining copies of drug labeling under FOIA would be time-consuming, difficult, or impractical. The comments suggested that FDA develop procedures to display such labeling or to provide them to applicants upon written or oral request. One comment also said that FDA should routinely provide ANDA applicants with updated labeling.

FDA disagrees that its FOIA system is inadequate for ANDA labeling purposes. The agency's FOIA system handles information requests in an orderly and expeditious manner. The procedure for requesting information is both simple and straightforward. (See 21 CFR 20.40.) Additionally, FDA regulations, in most instances, require the Freedom of Information Staff to respond to a freedom of information request within 10 working days. (See 21 CFR 20.41(b).) For these reasons, FDA declines to create an alternate system for providing drug labeling.

As for providing updated labeling information, the agency does not believe it is currently feasible to routinely provide updated labeling on all products eligible for ANDA's. The Office of Generic Drugs (OGD) encourages applicants to contact OGD before submitting an ANDA for advice on what labeling would be the most appropriate to use for its proposed product. Such

labeling can ordinarily be obtained from one or more of the following sources, including (1) OGD labeling guidance documents, (2) the innovator or generic drug product labeling from the product itself, (3) Physician's Desk Reference, (4) FDA's Freedom of Information Office, or (5) calling the Drug Information Services Branch directly at 301–443–3910. FDA also provides further guidance to an ANDA applicant after the applicant submits proposed labeling. After ANDA approval, FDA tracks the labeling status of the pioneer drug product and, if necessary, notifies ANDA holders when and how they must revise their labeling.

36. One comment asked FDA to clarify its policy regarding the use of the ANDA holder's name on the label and package insert when the ANDA holder neither manufactures nor distributes the drug product.

FDA's policy regarding the names on drug product labeling is set forth at 21 CFR 201.1 as authorized by section 502 of the act (21 U.S.C. 352). In general, § 201.1 states that, with few exceptions, no person other than the manufacturer, packer, or distributor may be identified on the label of a drug or drug product. The Orange Book discusses this subject in greater detail and recognizes that, under certain circumstances, the ANDA holder's name might not appear on the product's labeling. (See "Approved Drug Products with Therapeutic Equivalence Evaluations," pp. 1–3 (1991).)

37. One comment asked how ANDA applicants should present proposed labeling. The comment said that FDA should specify its exact requirements or permit applicants to submit labeling in any format they choose.

FDA believes that detailed instructions on the size and format of proposed labeling are not appropriate for this regulation. Applicants who have questions about the presentation of labeling in ANDA's should contact the Program Support Staff, Office of Generic Drugs, for guidance.

38. Proposed § 314.94(a)(8)(ii) would require ANDA applicants to provide copies of the label and labeling for the proposed drug product. Two comments suggested that FDA amend the rule to permit applicants to provide photographs of labeling rather than actual copies of the labeling when the label is printed on a tube or shipping carton.

FDA declines to accept the comment. Actual copies of tube labeling and other labeling help FDA determine the prominence of the information presented and whether the information is legible. These determinations cannot be easily made by the review of photographs. Ordinarily, however, FDA does not require submission of copies of shipping carton labeling as part of an abbreviated application.

39. Two comments opposed the requirement for a side-by-side comparison between the proposed ANDA drug product's labeling and the reference listed drug product's labeling under proposed § 314.94(a)(8)(iv). The comments said the comparison would be cumbersome and impractical, and suggested annotated changes or highlighted changes instead of comparisons.

In contrast, three comments supported side-by-side labeling but asked that ANDA holders be required to complete labeling revisions within 30 days of any change in the listed drug's labeling or to provide labeling comparisons every 6 months to ensure that the ANDA drug's labeling matched that of the listed drug. One comment said FDA should create a mechanism to compel ANDA holders to revise their labeling to conform to the listed drug product once the ANDA is approved.

The final rule retains the requirement of side-by-side labeling comparisons. Side-by-side comparisons enable FDA reviewers to readily identify differences between the ANDA applicant's and the innovator's product labeling. FDA does not believe that this requirement will impose a significant burden on ANDA applicants.

As for creating a mechanism to compel labeling revisions, section 505(e)(2) of the act authorizes the withdrawal of approval of an application if "there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof." This provision applies to both ANDA and NDA drug products. Because an ANDA must have labeling that is the same as the reference listed drug under section 505(j)(2)(A)(v) of the act, FDA believes that a generic drug product approved on the basis of studies conducted on the listed drug and whose labeling is inconsistent with the listed drug's labeling might not be considered safe and effective for use under the conditions prescribed, suggested, or recommended in the listed drug's labeling. FDA, therefore, has revised § 314.150 to permit the agency to withdraw approval of an ANDA if the applicant fails to maintain labeling in compliance with the requirements of the act.

As for requiring ANDA holders to submit drug labeling at periodic intervals, FDA believes that the existing reporting requirements at 21 CFR 314.70 and 314.81 ensure that labeling changes are brought to FDA's attention in an appropriate and timely fashion. The agency will advise ANDA holders of changes to be made after approval, but postapproval changes resulting from the expiration of exclusivity or patent protection are the responsibility of the ANDA holder.

40. Two comments said the labeling provisions should be revised to permit ANDA applicants to deviate from the labeling for the reference listed drug to add contraindications, warnings, precautions, adverse reactions, and other safety-related information. One comment added that ANDA applicants should be allowed to delete some of the indications contained in the labeling for the reference listed drug.

FDA disagrees with the comments. Except for labeling differences due to exclusivity or a patent and differences under section 505(j)(2)(v) of the act, the ANDA product's labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for ANDA approval. Consistent labeling will assure physicians, health professionals, and consumers that a generic drug is as safe and effective as its brand-name counterpart. (See 54 FR 28872 at 28884.) If an ANDA applicant believes new safety information should be added to a product's labeling, it should contact FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised. After approval of an ANDA, if an ANDA holder believes that new safety information should be added, it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised.

41. One comment suggested revising proposed § 314.94(a)(8)(iv) to exempt ANDA holders from being required to submit pharmocokinetic data to support new labeling unless the new labeling pertained to serious health or safety effects. The proposed provision stated that differences between an ANDA applicant's proposed labeling and the labeling approved for the reference listed drug may include, among other things, differences in pharmacokinetics. The comment explained that "insignificant labeling changes otherwise could become a tool to impede the ability of generics to compete, or force them to raise prices to the consumer in order to absorb the cost of additional, insignificant and, perhaps, unnecessary pharmacokinetic studies."

The comment misinterpreted the proposed requirement. The provision

does not impose a pharmacokinetic data requirement for all labeling changes. In fact, FDA believes that most labeling changes that do not involve serious health or safety effects will be acceptable without new pharmacokinetic data. However, FDA also believes that some labeling changes may be formulation-specific and that such changes may require additional pharmacokinetic data (e.g., addition of a food effect statement). FDA, therefore, reserves the right to examine such labeling changes on a case-by-case basis to determine whether additional pharmacokinetic data are necessary before the ANDA holder changes labeling.

42. One comment proposed revising the third sentence in proposed § 314.194(a)(8)(iv), which listed certain permissible labeling differences between the ANDA drug product and the reference listed drug, to read as follows:

> Such differences protected by patent or accorded exclusivity by 505(j)(4)(D) of the act between the applicant's proposed labeling and labeling approved for the reference listed drug may include differences in expiration date, formulation, bioavailability, or pharmacokinetics, labeling revisions made to comply with current FDA labeling guidelines or other guidance, or omission of an indication protected by patent or accorded exclusivity under section 505(j)(4)(D) of the act.

The comment explained that the revision would protect ANDA applicants from "a possible claim of inducement or infringement where a nonapproved, but patented, method of administration is discussed in the innovator's label" or the labeling refers to more than one method of use and "some but fewer than all of the methods of use are entitled to nonpatent exclusivity."

FDA agrees in part with the comment and has amended the provision to state that differences between the applicant's proposed labeling and labeling approved for the reference listed drug may include omissions of an indication "or other aspect of labeling protected by patent or accorded exclusivity under section 505(j)(4)(D) of the act."

Chemistry, Manufacturing, and Controls

FDA received a number of comments on the chemistry, manufacturing, and controls section of an ANDA.

43. Many comments sought further definitions or explanations regarding ANDA chemistry, manufacturing, and controls documentation requirements, including information on technical details, such as determining the source of impurities, potential degradation, and test methodologies. Two comments asked FDA to develop guidelines on acceptable levels of preservatives and other inactive ingredients.

These comments raise technical questions that are beyond the scope of this rule. FDA has already issued a number of guidelines addressing many of the questions. These guidelines apply to both full and abbreviated applications, and a list of available guidelines may be obtained from CDER Executive Secretariat Staff, Center for Drug Evaluation and Research (HFD-8), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. FDA will consider the comments in determining whether to revise existing guidelines or to develop new guidelines.

44. Several comments objected to the provisions in proposed § 314.94(a)(9) requiring ANDA applicants to use the same inactive ingredients as the reference listed drug or to identify and characterize the differences between inactive ingredients. The comments stated that ANDA applicants might not know or might be unable to discover all inactive ingredients used in the reference listed drug. The comments suggested that FDA either not require that the inactive ingredients be the same or require the disclosure of the inactive ingredients used in the reference listed drug.

Because the labeling regulations do not require listing of inactive ingredients for drug products in an oral dosage form (see 21 CFR 201.100(b)(5)), ANDA applicants may be unable to discover what inactive ingredients were used in such drug products. Consequently, FDA has revised § 314.94(a)(9) to require ANDA applicants to include such a comparison only for drug products intended for parenteral use, ophthalmic or otic use, or topical use. ANDA applicants will be able to determine the inactive ingredients in reference listed drugs for these dosage forms because such ingredients are disclosed on the labeling. (See 21 CFR 201.100(b)(5).) For other drug products, FDA has revised § 314.94(a)(9)(ii) to require applicants only to identify and characterize the inactive ingredients in the proposed drug product and to provide information demonstrating that the inactive ingredients do not affect product safety.

45. Proposed § 314.94(a)(9)(iv) stated, in part, that:

> * * * an applicant may seek approval of a drug product (intended for ophthalmic or otic use) that differs from the reference listed drug in preservative, buffer, substance to adjust tonicity, or thickening agent provided that the applicant identifies and characterizes the differences and provides information demonstrating that the differences do not affect the safety of the proposed drug product, except that in a product intended for ophthalmic use, an applicant may not change a buffer or substance to adjust tonicity for the purpose of claiming a therapeutic advantage over or difference from the listed drug, e.g., by using a balanced salt solution as a diluent as opposed to an isotonic saline solution, or by making a significant change in the pH or other change that may raise questions of irritability.
>
> (54 FR 28872 at 28923).

One comment objected to the example involving balanced salt solutions and isotonic saline solutions in proposed § 314.94(a)(9)(iv). The comment explained that changes in an ophthalmic buffer or tonicity agent from isotonic saline to balanced salt solutions do not raise serious safety questions, and FDA cannot presume that such changes are to claim a therapeutic advantage.

When read in its entirety, the second sentence in § 314.94(a)(9)(iv) simply states that an applicant whose product is intended for ophthalmic use cannot change a buffer or substance to adjust tonicity "for the purpose of claiming a therapeutic advantage over or difference from the listed drug * * *." The rule does not state that use of a balanced salt solution as opposed to an isotonic saline solution would be impermissible in itself or that FDA would presume such changes to be for claiming a therapeutic advantage. Determining whether the applicant claims a therapeutic advantage over or difference from the listed drug depends on the circumstances surrounding each case.

Samples

46. FDA received one comment regarding generic drug product samples under proposed § 314.94(a)(10). The proposed rule would require ANDA applicants to comply with the sampling provisions at 21 CFR 314.50 (e)(1) and (e)(2) but would not require ANDA applicants to submit samples until FDA requested them. The comment suggested revising the rule to require ANDA applicants to obtain samples and to retain them in their stability containers for all lots of a finished product. The comment added that FDA should "make itself available as a witness if requested for the distribution of samples to laboratories for bioavailability studies."

Under existing current good manufacturing practice (CGMP) regulations, manufacturers are already required to retain samples. (See 21 CFR 211.84 and 211.170.) FDA has also issued an interim rule that requires applicants who conduct in-house bioavailability and bioequivalence testing and contract laboratories who conduct such testing to

retain reserve samples of the drug products used to conduct the studies. The interim rule, which appeared in the **Federal Register** of November 8, 1990 (55 FR 47034), and existing CGMP regulations will help FDA ensure that the samples sent to laboratories match the drug product to be produced. Therefore, the suggestion that FDA be available to witness distribution of samples to laboratories is unnecessary. FDA anticipates publication of a final rule shortly.

Patent Certification

FDA received a number of comments regarding patent certifications under proposed § 314.94(a)(12). The agency is still examining these comments and will finalize the provisions for patent certification at a later date.

DESI Drugs

47. Two comments objected to the inclusion in proposed § 314.94(b) of DESI drugs in the ANDA regulations. The proposed rule would permit persons to file ANDA's for a duplicate of a drug product that is subject to the DESI review or a DESI-like review and also a listed drug. If the ANDA is for a drug product that is a duplicate of a drug product that is subject to the DESI review or a DESI-like review and not listed, the proposed rule would require applicants to comply with the conditions set forth in the applicable DESI notice or other notice with respect to conditions of use and labeling and the ANDA content and format requirements. One comment argued that the statute applies only to post-1984 ANDA's so including DESI drugs was inappropriate. The comment suggested deleting this provision but noted that "additional special considerations need to be recognized" when finalizing the rule because, for some DESI active ingredient categories, there is no readily identifiable pioneer NDA product. A second comment stated that, under proposed § 314.94(b)(2), DESI drugs cannot be reference listed drugs unless they are listed or the applicant has filed an application under section 505(b)(1) or (b)(2) of the act.

The ANDA provisions of the 1984 amendments are applicable to all generic drugs for which approval is sought after September 24, 1984, the date on which the statute was enacted. However, after careful consideration, FDA agrees that ANDA's are inappropriate if the drug product that is the subject of a DESI review or DESI-like review has not complied with the conditions for effectiveness set forth in a DESI notice or other notice. In the absence of an approved product that satisfies the conditions set forth in the DESI notice or other notice, there is no "listed drug" within the provisions of section 505(j)(6) of the act, and an ANDA cannot be submitted for that drug.

Therefore, FDA will no longer accept an ANDA for a DESI drug product when there is no listed drug for that product, and has deleted § 314.94(b)(2) entirely. An applicant seeking approval of a drug product covered by a DESI upgrade notice before a product is approved for safety and effectiveness under that notice should submit a 505(b)(2) application to the Office of Generic Drugs. Generally the 505(b)(2) application must contain the information specified in section 505(b)(2) of the act, except that the labeling must meet the conditions of use announced as effective in the relevant DESI upgrade notice. In satisfying the full reports of investigations requirement under section 505(b)(1)(A) of the act, the applicant may refer to the agency's conclusions in the DESI upgrade notice about the product's safety and effectiveness and must demonstrate that the proposed drug product is bioequivalent to the drug product that is the subject of the relevant DESI upgrade notice. The agency will generally employ the same mechanisms and standards in approving a section 505(b)(2) application for a DESI drug product that it would for and ANDA under section 505(j).

Section 314.96—Amending an Unapproved ANDA

FDA received a small number of comments concerning proposed § 314.96. The proposed rule would permit applicants to amend an ANDA that had been submitted, but not yet approved, to revise existing information or to provide additional information. The proposed rule also explained when an amendment might extend the review period.

48. One comment objected to a preamble statement which said "data from a bioequivalence study where only a protocol was contained in the original submission" could be an example of a major ANDA amendment. (See 54 FR 28872 at 28888.) The comment said that an ANDA application should be complete when submitted and not completed through amendments.

FDA agrees with the comment. Under current policy, FDA does not accept an ANDA that contains only a bioequivalance study protocol. This policy is consistent with the statutory provision requiring an ANDA to contain information showing that the applicant's drug product is, rather than "will be shown to be," bioequivalent to the reference listed drug. (See 21 U.S.C. 355(j)(2)(A)(iv).)

49. One comment asked whether ANDA applicants could amend applications without informing FDA of their intent to amend them or withdraw applications after receiving an approvable or not approvable letter.

Under 21 CFR 314.110(b), an ANDA applicant who has received an approvable letter must correct the deficiencies described in the approvable letter "by amendment within the specified time period" or FDA will refuse to approve the abbreviated application. The ANDA applicant may also ask the agency to provide an opportunity for a hearing. Under 21 CFR 314.120(b), an ANDA applicant who has received a not approvable letter must amend or withdraw the ANDA or notify FDA of an intent to file an amendment within 180 days after the date of the not approvable letter. Under 21 CFR 314.120(a)(3), an ANDA applicant may also ask the agency to provide an opportunity for a hearing. If an ANDA applicant fails to respond within 180 days to the not approvable letter, FDA will consider the ANDA applicant's failure to respond to be a request to withdraw the ANDA. Thus, an ANDA applicant that receives an approvable or not approvable letter may amend its ANDA without informing FDA of its intent to amend the ANDA. The regulations also do not require ANDA applicants to provide notice of intent to withdraw an ANDA.

50. Several comments discussed "major" and "minor" amendments in relation to proposed § 314.96(a)(2) and (a)(3). Proposed § 314.96 (a)(2) would permit FDA to extend the review period if the amendment contained significant new data requiring additional time for agency review. Proposed § 314.96(a)(3) would treat the submission of an ANDA amendment to resolve substantial deficiencies as set forth in a not approvable letter as an agreement between FDA and the applicant to extend the review period 120 days. Neither provision referred to "major" or "minor" amendments, but the preamble to the proposed rule explained that a major amendment would be one which required substantial review time. The preamble provided several examples of such major amendments, including amendments containing data from a new bioequivalence study or stability or sterility study submitted in support of a drug product reformulation or changes in the manufacturing or controls procedures.

One comment stated that an amendment, regardless of whether it

was a "major" or "minor" amendment, should not result in any extension of the review period if FDA had not begun to review the application. This comment also suggested that "minor" amendments, which it defined as requiring less than 8 hours of review time, only result in a 14-day extension to the review period.

FDA disagrees with the comment. A policy that would permit applicants to submit amendments containing significant data or information without extending the review period would encourage the submission of incomplete ANDA's and create new administrative problems between applicants and the agency. For example, disputes would arise as to whether an amendment had been submitted before review had begun or whether a particular FDA action constituted "review."

As for extension periods, FDA has decided not to adopt proposed § 314.96(a)(2). The agency found the proposed provision to be unfeasible and has decided to retain the concepts at § 314.60. Consequently, FDA has revised § 314.96(a)(2) to state that an amendment containing significant data or information requiring additional time for agency review will constitute an agreement by the applicant to extend the date by which the agency is required to reach a decision on the application. The revised paragraph states that FDA will ordinarily extend the review period "only for the time necessary to review the significant data or information," and this period will not exceed 180 days. This paragraph, as revised, is similar to the preexisting requirements under § 314.60 and encourages ANDA applicants to submit complete applications.

Proposed § 314.96(a)(2) also stated that FDA would notify an applicant of the length of the extension. The agency has decided not to adopt the notification provision. FDA's experience suggests that it is difficult and impractical to predict the length of an extension for an ANDA given the unpredictable nature of its workload. At the same time, FDA emphasizes that extensions under this paragraph will be "only for the time necessary to review the new information." The agency hopes to be able to limit extensions under § 314.96(a)(2), which applies to amendments submitted other than in response to a not approvable letter, to generally not more than 120 days if resources permit.

With regard to the comment regarding "minor" amendments, under current Office of Generic Drugs policy, FDA distinguishes between major and minor amendments only with regard to amendments submitted in response to a not approvable letter. These are covered under § 314.96(a)(3).

51. Three comments concerned extending the review period for amendments under proposed § 314.96(a)(3). One comment suggested that the extension be "not more than 120 days." Another comment said major amendments responding to FDA reviewers should not constitute an agreement to extend the review period. This comment added that if an extension were necessary, "it should not affect the entire ANDA, but only the discipline in which it is generated." The third comment objected to § 314.96(a)(3) entirely and claimed, without explanation, that it was inconsistent with the statute.

As stated above with regard to § 314.96(a)(2), FDA has decided against the adoption of proposed § 314.96(a)(3) and, instead, has revised § 314.96(a)(3) to state that the submission of an amendment containing significant data or information to resolve deficiencies in the application as set forth in a not approvable letter constitutes an agreement between FDA and the applicant to extend the review period. This paragraph, as revised, corresponds to similar requirements under § 314.60. The extension will only be for the time necessary to review the significant data or information and would not exceed 180 days.

FDA notes that under current Office of Generic Drugs policy, FDA distinguishes between major and minor amendments submitted in response to not approvable letters. (See memorandum issued July 11, 1991, from the Director, Office of Generic Drugs, to Office Division Directors, Deputy Division Directors, Associate Office Directors, and Branch Chiefs). FDA currently considers a minor amendment to be one that an experienced chemist reasonably can be expected to take less than 1 hour to complete the review. Under current policy, FDA commits to make every attempt to take action on a minor amendment within 60 days of its receipt, subject to applicable agency clearances such as a field inspection or microbiology consult.

Although the agency would like to be able to review all major amendments and applications within the 180-day period provided by statute, and would like to establish goals for reviewing these submissions in even shorter time periods, current resources do not provide a basis for establishing such goals for the foreseeable future. The Agency's goal at this time is to meet its obligations under the statute and to review these submissions as efficiently and as expeditiously as possible without affecting the scientific integrity of the review.

The agency disagrees, however, with the comments that would prevent the agency from extending the review period. FDA's experience indicates that some amendments that are intended to respond to not approvable letters can be extremely complex and present new information. If the agency could not extend the review period after receiving such amendments, the only practical recourse would be not to approve the application and have the applicant submit a new ANDA. This would be inefficient and wasteful, so § 314.96(a)(3) treats an amendment under this paragraph as an agreement to extend the review period. This permits both FDA and the applicant to continue working on the ANDA.

FDA emphasizes, however, that an applicant who receives a not approvable letter and wishes to submit an amendment to resolve the deficiencies identified in the not approvable letter should confine its amendment to the subjects discussed in the letter. Completely new information on topics not raised in the not approvable letter only prolongs FDA review.

FDA disagrees with the comment claiming that the provision is inconsistent with the statute. Under section 505(j)(4)(A) of the act, FDA must approve or disapprove an application within 180 days after its initial receipt or "within such additional period as may be agreed upon * * *." The statute clearly recognizes that deciding whether to approve an application may require more than 180 days.

52. One comment said FDA should, upon submission of an ANDA, notify the applicant of the date on which the agency would approve or not approve the ANDA. Alternatively, the comment would require FDA to review an ANDA once it had been submitted to determine whether the application may be received.

FDA declines to adopt the comment. Under § 314.101(b)(2), FDA will notify applicants, in writing, whether the agency will receive an ANDA. (Such written notice, however, is not provided when FDA receives an ANDA supplement.) FDA will not, however, create a deadline for informing applicants whether an ANDA is received because such deadlines would be impractical. FDA cannot predict the number of applications it will receive in any given period and must remain flexible to assign its staff to respond to agency demands and priorities. As for notifying applicants of the latest date on

which FDA should approve or not approve an ANDA, § 314.100(a) states that FDA will send an ANDA applicant an approval letter, approvable letter, or not approvable letter within 180 days of receipt of an ANDA.

Section 314.97—Supplements and Other Changes to an Approved Abbreviated Application

FDA received no comments on this provision and has finalized it without change.

Section 314.98—Postmarketing Reports

Proposed § 314.98 would require an applicant that has an approved abbreviated antibiotic application or approved ANDA to comply with adverse drug experience reporting requirements. Proposed § 314.98(c), however, would not require holders of approved ANDA's or abbreviated antibiotic applications to submit periodic reporting of adverse drug experiences "if no adverse drug experience reports have been received and no labeling changes have been initiated by the applicant during the reporting interval."

53. Several comments, however, said postmarketing report requirements should be the same for NDA and ANDA holders. One comment said FDA should require ANDA holders to submit a periodic report that would indicate whether a company had received any adverse drug experience reports during the reporting period.

After careful consideration, FDA has revised § 314.98 to require ANDA applicants to submit a periodic report of adverse drug experiences even if the ANDA applicant has not received any adverse drug experience reports or initiated any labeling changes. As revised, the requirement is identical to that imposed on NDA holders. Periodic reports by ANDA holders will help FDA determine whether ANDA products have appropriate labeling and ensure that no adverse drug experiences go unreported.

54. FDA, on its own initiative, has amended § 314.98(a) to require abbreviated antibiotic application and ANDA applicants to comply with the recordkeeping requirements under § 314.80. This change corrects an inadvertent omission from the original proposal.

Section 314.99—Other Responsibilities of an Applicant of an Abbreviated Application

FDA received no comments on this provision and has finalized it without change.

Section 314.100—Timeframes for Reviewing Applications and Abbreviated Applications; Section 314.101—Filing an Application and an Abbreviated Antibiotic Application and Receiving an Abbreviated New Drug Application

Proposed § 314.100 discussed timeframes for reviewing applications and abbreviated applications. In general, the proposed rule would have FDA review an application or abbreviated application and send the applicant an approval letter, approvable letter, or not approvable letter within 180 days of receipt of an application under section 505(b) of the act, or an ANDA under section 505(j) of the act, or an abbreviated antibiotic application under section 507 of the act. Proposed § 314.101 concerned the circumstances under which FDA would file an application and an abbreviated antibiotic application and receive an ANDA. FDA received several comments suggesting additional agency obligations when an application or abbreviated antibiotic application is filed and when an ANDA is received.

55. One comment wanted the agency to amend proposed § 314.100 to require FDA to acknowledge receipt of an application and to issue an application number. The comment suggested that this occur within 14 days after the application is submitted.

Section 314.101 states that FDA will notify applicants, in writing, whether an application or abbreviated application is filed or received. (See 21 CFR 314.101(a)(2) and (b)(2).) These letters should contain an application number. As noted in paragraph 52 above, FDA believes that establishing a fixed time period for determining whether an application may be received would be impractical considering the number of applications and supplements FDA receives. As a result, FDA declines to amend the rule as requested.

56. Two comments suggested that either proposed § 314.100 or § 314.101 be amended to have FDA expressly determine whether an ANDA is "received" within 30 days of its submission.

FDA declines to accept the comments. As stated earlier, FDA cannot predict how many applications will be submitted in a given period, so it must retain flexibility to respond to any demands imposed on the agency. Creating an additional 30-day deadline in the ANDA review process would limit that flexibility without any significant benefit to FDA or to applicants.

57. Another comment said proposed § 314.101(b) should not authorize FDA to determine whether an abbreviated application may be received.

FDA rejects this comment. By determining whether an application is "received," FDA encourages applicants to submit ANDA's that comply with statutory and regulatory requirements and are sufficiently complete for substantive review to begin. This conserves FDA resources by permitting FDA reviewers to devote their time to examining reviewable applications.

58. Two comments stated that an ANDA lacking bioequivalence or bioavailability information, completed bioequivalence studies, or stability data to support at least a 24-month expiration date should not be received.

As stated earlier, FDA no longer accepts an ANDA that lacks complete bioequivalence or bioavailability information at the time of its initial submission. Consequently, the agency has deleted § 314.101(d)(8), which pertained to ANDA's that did not contain the results of any required or completed bioequivalence or bioavailability study.

As for the comment suggesting that an ANDA lacking stability data to support at least a 24-month expiration date not be received, FDA declines to adopt the comment. Although most ANDA's contain such stability data, applicants have submitted and FDA has approved ANDA's containing stability data that support a different expiration date.

59. FDA received two comments on proposed § 314.101(e)(1). The proposed provision stated that FDA will refuse to file an application or abbreviated antibiotic application or consider an ANDA not to have been received if the drug product that is the subject of the submission "is already covered by an approved application or abbreviated application and the applicant of the submission is merely a distributor and/or repackager of the already approved drug product." One comment suggested that the first sentence be revised to state that FDA "may refuse to file" an application or abbreviated application if any of the listed conditions apply. The comment explained that FDA should have discretion to file an application, notwithstanding the existence of an approved application, when the applicant could justify the need for the duplicate application or abbreviated application. The second comment asked FDA to file duplicate ANDA's if two or more companies jointly develop the product or if an exclusive licensee or distributor seeks to file an ANDA with the licensor's consent.

Section 314.101(e)(1) was intended to prevent distributors from forcing FDA to

review applications for drug products that are already covered by approved applications. Reviewing an application is extremely time-consuming, and FDA's resources are limited. To permit applicants to force review of an application for a product that is already covered by an approved application would result in a severe drain on FDA resources to review duplicate applications, create duplicate product and patent listings in the Orange Book, and contribute to the agency's accumulation of applications. FDA did not, however, intend to apply this provision against companies that jointly develop a product. The agency, therefore, is amending § 314.101 to change the refusal in proposed § 314.101(e)(1) to accept duplicate applications to a discretionary refusal to accept duplicate applications under a new § 314.101(d)(8). FDA has also revised § 314.101(d)(8) to clarify that the agency may refuse to file an application or refuse to consider an ANDA to be received for a drug product when the application already has an approved application or abbreviated application for the same drug product.

Additionally, the agency has created a new § 314.101(d)(9) to clarify that the agency may refuse to file a 505(b)(2) application for a drug that is a duplicate of a listed drug and is eligible for approval under section 505(j) of the act.

60. One comment asked FDA to amend § 314.101(f)(2) to add time periods for setting a hearing date following ANDA disapproval and for issuing a decision on a hearing. The comment also requested procedures for appealing a disapproval that would give the applicant "immediate attention" and be considered to be "final agency action."

The regulation pertaining to not approvable letters to applicants, § 314.120, states that when the agency refuses to approve an application, abbreviated antibiotic application, or ANDA, it will give the applicant a written notice of an opportunity for a hearing under § 314.120(a)(3). Section 314.200 states that, if the Commissioner of Food and Drugs grants a hearing, the hearing will begin within 90 days after the expiration of the time for requesting the hearing unless the parties otherwise agree in the case of denial of approval, and as soon as practicable in the case of withdrawal of approval (§ 314.200(g)(5)). Thus, there is no need to amend § 314.101(f)(2) to set a hearing date.

FDA also declines to set a deadline for resolving hearings or appeals. The demands placed on the presiding officer and other FDA employees assigned to administrative hearings can be immense depending on, among other things, the number of documents submitted to the administrative record. A large administrative record, coupled with the other obligations placed on the agency's employees, makes a deadline for resolving these matters impractical.

Finally, the administrative hearing regulations contain procedures for appealing a disapproval (e.g., 21 CFR 10.33 and 10.35). Parties may also seek judicial review as provided in 21 CFR 314.235(b).

Section 314.102—Communications Between FDA and Applicants

FDA received four comments regarding communications between FDA and applicants under proposed § 314.102. The proposed rule was substantially similar to the existing provision at 21 CFR 314.102 with the exception of new language to account for abbreviated applications and the availability of conferences and meetings for abbreviated applications. Proposed § 314.102(b) said FDA reviewers would make every reasonable effort to inform applicants of easily correctable deficiencies found in an application or abbreviated application or whether the agency would need more data or information. Proposed § 314.102(c) provided for 90-day conferences "to inform applicants of the general progress and status of their applications, and to advise applicants of deficiencies which have been identified by that time and which have not already been communicated." These conferences would be available for applications for all new chemical entities and major new indications of marketed drugs. Proposed § 314.102(d) would provide end-of-review conferences "to discuss what further steps need to be taken by the applicant before the application or abbreviated application can be approved." Finally, proposed § 314.102(e) indicated that applicants could request other meetings to discuss scientific, medical, or other issues.

61. One comment would require FDA reviewers to call ANDA applicants before issuing deficiency letters. The comment claimed FDA reviewers misinterpret or misread applications and could resolve these misunderstandings without a deficiency letter if they called ANDA applicants.

FDA declines to adopt the comment. The agency fully intends to communicate with ANDA applicants to resolve issues that arise during the ANDA review process but believes that requiring FDA reviewers to call ANDA applicants would be impractical and an inefficient use of resources. Some issues cannot be resolved or adequately described in a telephone call.

62. One comment proposed amending § 314.102(d) to require FDA to hold an end-of-review conference within 30 days of the issuance of a not approvable letter. Two comments addressed meetings under proposed § 314.102(e). One comment would require FDA reviewers and chemists to meet with any applicant upon 30 days notice. Finally, another comment urged FDA to be "liberal and speedy in granting requests for meetings on issues that arise during the review process."

FDA declines to accept the comments. FDA will make every attempt to grant requests for meetings that involve important issues, but, due to limited resources and other demands on reviewers, will not conduct meetings on a regular basis. The agency reiterates that 90-day conferences are available "on applications for all new chemical entities and major new indications of marketed drugs" (21 CFR 314.102(c) (emphasis added)), and that end-of-review conferences are available on all applications and abbreviated applications "with priority given to applications for new chemical entities and major new indications for marketed drugs and for the first duplicates for such drugs" (21 CFR 314.102(d)). Thus, for ANDA's, 90-day conferences will generally be unavailable, and end-of-review conferences will be given low priority.

FDA adds that ANDA applicants who do request a meeting are encouraged to submit an agenda of important issues in advance for FDA's consideration. This will permit the agency to focus on specific issues and conserve resources.

Section 314.103—Dispute Resolution

FDA received no comments on this provision and has finalized it without change.

Section 314.104—Drugs with Potential for Abuse

63. Only one comment addressed proposed § 314.104, which states that FDA will inform the Drug Enforcement Administration (DEA) when an application or abbreviated application is submitted for a drug that appears to have an abuse potential. The comment supported the rule but asked FDA to "ensure the confidentiality of any information, including even the fact that an application has been submitted prior to providing that information to DEA."

Section 314.104 simply reflects FDA's obligation, under 21 U.S.C. 811(f), to forward to DEA information on any drug having a stimulant, depressant, or

hallucinogenic effect on the central nervous system if "it appears that such drug has abuse potential." (See 21 U.S.C. 811(f).) FDA's disclosure of information to another Federal agency does not necessarily result in the public disclosure of that information. (See 21 CFR 20.85.) Indeed, the regulation on public disclosure of information at § 314.430 states that FDA will not publicly disclose the existence of an application or an abbreviated application before sending the applicant an approval letter unless the application or abbreviated application's existence has been previously publicly disclosed or acknowledged (21 CFR 314.430(b)). This includes data in an application or abbreviated application (21 CFR 314.430(c)). Disclosure of any trade secret information obtained under section 505 of the act is also prohibited by section 301(j) of the act.

Section 314.105—Approval of an Application and an Abbreviated Application

64. FDA received two comments on proposed § 314.105(d). Under that provision, FDA will approve an ANDA and send the applicant an approval letter if the agency finds none of the grounds for refusing ANDA approval to apply. Both supported the rule, but one comment said an approval letter should not raise any new issues "except on the data submitted in response to an approvable letter."

With the exception of editorial matters or other minor deficiencies in an ANDA, approval letters should not raise new issues for applicants to resolve. Therefore, the comment's suggestion is unnecessary.

FDA has, on its own initiative, clarified that an approval with a delayed effective date is tentative and does not become final until the effective date. The agency has also amended § 314.105(c) to state that an abbreviated application must meet statutory standards for manufacturing and controls, labeling, and "where applicable, bioequivalence." This change reflects the statutory requirements for an ANDA.

Section 314.110—Approvable Letter to the Applicant

FDA received seven comments regarding approvable letters to applicants under proposed § 314.110. The proposed rule stated that FDA would send applicants an approvable letter "if the application or abbreviated application substantially meets the requirements of this part and the agency believes that it can approve the application or abbreviated application if specific additional information or material is submitted or specific conditions * * * are agreed to by the applicant." Proposed § 314.110 (a)(1) through (a)(5) would give those submitting full or abbreviated antibiotic applications 10 days to respond to or act on an approvable letter, request a hearing, or agree to an extension of the review period. Under proposed § 314.110(b), FDA would send approvable letters to ANDA applicants only if the ANDA substantially meets FDA requirements and the agency believed that "it can approve the abbreviated application if minor deficiencies in the draft labeling are corrected and final printed labeling is submitted." The proposed rule did not give ANDA applicants a specific time period to respond to an approvable letter.

65. Two comments recommended revising proposed § 314.110(a)(3). That provision stated that an NDA applicant who receives an approvable letter may ask FDA to provide an opportunity for a hearing on the question of whether there are grounds for denying approval of the application under section 505(d) of the act. One comment urged FDA to provide an opportunity for a hearing to ANDA applicants. The second comment suggested revising the rule to provide hearing dates.

With respect to ANDA applicants, FDA is amending § 314.110(b) to permit ANDA applicants to request, within 10 days after the date of an approvable letter, that FDA provide an opportunity for a hearing. This is consistent with the opportunity for a hearing provided to applicants who receive a not approvable letter under § 314.120, although the agency believes that most issues raised by approvable letters should be capable of being resolved without a hearing. The agency is also amending § 314.110(a)(3) to note that abbreviated antibiotic applications applicants will have an opportunity to request a hearing under § 314.125. The proposed rule inadvertently omitted such language even though §§ 314.101 and 314.125 suggested that these applicants had an opportunity for a hearing.

As for providing hearing dates, FDA believes that amending the rule to provide hearing dates would be impractical. FDA's experience with scheduling administrative hearings shows that finding mutually acceptable hearing dates can be difficult, and the parties often request postponements even after a hearing date has been set.

66. Two comments suggested that FDA prescribe time limits for its review of amendments submitted in response to an approvable letter. One comment would require FDA to review an ANDA applicant's response to an approvable letter within 45 days. A second comment would require FDA to review an ANDA applicant's response within 90 days.

FDA declines to amend the rule as suggested. Under § 314.110(b), FDA will send an approvable letter to an ANDA applicant only if the ANDA meets regulatory requirements under 21 CFR part 314 and FDA "believes that it can approve the abbreviated application if minor deficiencies are corrected * * *." However, FDA's ability to review an applicant's response to an approvable letter can vary due to a number of factors, such as the reviewer's skill, speed, and work load, the quality of the amendment or submission, and the complexity of the issues. Thus, the final rule does not require the agency to review an applicant's response within a single, predetermined time period. Unless the applicant's response to the approvable letter contains significant data or information requiring an extension of the review period, FDA should complete, and has the goal of completing, most of these reviews before 60 days have expired.

67. Two comments asked FDA to clarify when it would issue an approvable letter to an ANDA applicant. Under proposed § 314.110(b), FDA would send an ANDA applicant an approvable letter "only if the application substantially meets the requirements of this part and the agency believes that it can approve the abbreviated application if minor deficiencies in the draft labeling are corrected and final printed labeling is submitted." One comment said an approvable letter should be appropriate for more than minor labeling changes, and should also be used for changes such as a change in U.S.P. requirements, or the addition or deletion of an alternate analytical method. The second comment asked FDA to define the phrase, "substantially meets the requirements of this part."

FDA agrees that approvable letters may be appropriate for more than minor labeling deficiencies. Consequently, the agency has revised the rule to state that minor labeling deficiencies are simply an example of the type of deficiencies for which an approvable letter may be appropriate.

As for the phrase, "substantially meets the requirements of this part," FDA means that, with the exception of minor deficiencies, the ANDA complies with the requirements under 21 CFR part 314.

Section 314.120—Not Approvable Letter to the Applicant

Proposed § 314.120 described the circumstances under which FDA would send a not approvable letter. Proposed § 314.120(a)(1) and (a)(2) would require applicants to amend, withdraw, or notify FDA of an intent to amend an application or abbreviated application. Proposed § 314.120(a)(3) would permit applicants to ask FDA to provide a hearing on the question of whether there are grounds for denying approval of the application under section 505(d) or (j)(3) of the act. Applicants would be required to respond to a not approvable letter within 10 days, except that ANDA applicants, under proposed § 314.120(b), would have 180 days to respond.

68. Most comments on proposed § 314.120 recommended changes to response times. One comment suggested amending § 314.120(a) to give applicants 30 days to respond to a not approvable letter. Two comments asked that the regulation require ANDA applicants to respond to a not approvable letter within 10 days rather than the 180 days given at § 314.120(b).

FDA declines to amend the rule as suggested by the comments. The comments did not contain any justification for revising the response times, and FDA sees no reason to do so.

69. One comment asked that proposed § 314.120(a)(3) be revised to make clear that ANDA and NDA applicants, upon receipt of a not approvable letter, have the right to request that the agency provide the applicant an opportunity for a hearing.

Section 314.120(a)(3) was intended to apply to both ANDA applicants and to NDA applicants. FDA, therefore, agrees with the comment and has revised the provision accordingly. FDA has also revised § 314.120(b) to clarify that an ANDA applicant must make its request for a hearing to FDA within 10 days after the date of the not approvable letter.

Section 314.122—Submitting an Abbreviated Application for, or a 505(j)(2)(C) Petition That Relies on, a Listed Drug That is no Longer Marketed

70. One comment suggested that the title be revised to read, "Submitting an Abbreviated Application for * * *." The comment said this change would be consistent with the definitions in § 314.3.

FDA agrees and has revised the title accordingly.

Section 314.125—Refusal to Approve an Application or an Abbreviated Antibiotic Application

FDA received no comments on this provision and has finalized it without substantive change.

Section 314.127—Refusal to Approve an Abbreviated New Drug Application

Proposed § 314.127 provided a list of reasons for refusing to approve an ANDA. In general, these reasons corresponded to those listed at section 505(j)(3) of the act.

71. One comment asked FDA to amend proposed § 314.127(c) to describe the type of information that it would require an ANDA applicant to submit to show that an active ingredient in an ANDA product is the same as the active ingredient in the reference listed drug. In brief, proposed § 314.127(c) would, in relevant part, have FDA refuse to approve an ANDA if there is insufficient information to show that the active ingredient(s) in the proposed drug product are the "same" as those in the reference listed drug.

Under 21 CFR 314.120, if FDA believes that an application is not approvable, it will notify the applicant in writing and describe the deficiencies in the application. Thus, in the situation described by the comment, the applicant could use the agency's written response to determine how it could demonstrate that its active ingredient is the same as that in the reference listed drug. Depending upon the circumstances, an applicant might find additional guidance in drug compendia or FDA guidelines. (See paragraph 26 above for a related comment.) The comment's suggestion, therefore, is unnecessary.

72. Proposed § 314.127(g) (now § 314.127(a)(7)) would permit FDA to refuse to approve an abbreviated application if information in the ANDA "is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug * * * except for changes required because of differences approved in a petition under § 314.93 or because the drug product and the reference listed drug are produced or distributed by different manufacturers." One comment said FDA should also require ANDA holders to obtain current labeling for the listed drug every 6 months and update their own labeling accordingly.

FDA has revised § 314.150 to require ANDA holders to maintain current labeling. Failure to do so may result in withdrawal of approval. FDA will not, however, require ANDA holders to obtain current labeling or to update their own labeling every 6 months because drug labeling does not change on a regularly scheduled basis.

73. A second comment recommended adding "or because of patent requirements" to the end of proposed § 314.127(g).

FDA agrees that a patent may be a valid reason for labeling differences between the reference listed drug and the ANDA drug product and that such differences should not be a basis for refusing to approve an ANDA. FDA has, therefore, revised the rule to indicate that labeling differences may also be due to patents or exclusivity. However, FDA cautions that it will not approve an ANDA with different labeling if the labeling differences affect product safety or efficacy. For example, if the patent protects information on a new dosing regimen and FDA concludes that the preexisting dosing regimen is unsafe, the different labeling for the proposed ANDA product would be grounds for refusing to approve the ANDA.

74. Proposed § 314.127(h)(1)(i) (now § 314.127(a)(8)(i)(A)) would permit FDA to refuse to approve an ANDA if FDA had any information that the proposed drug product's inactive ingredients are unsafe for use under the conditions prescribed, recommended, or suggested in the proposed drug product's labeling. Proposed § 314.127(h)(1)(ii) (now § 314.127(a)(8)(i)(B) would permit FDA to refuse to approve an ANDA if the proposed drug product's composition was unsafe under the conditions prescribed, recommended, or suggested in the proposed labeling because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included. One comment asked FDA to merge proposed § 314.127(h)(1)(i) and (h)(1)(ii) or to explain their differences.

FDA declines to revise the rule as suggested. Section 314.127(a)(8)(i)(A) and (a)(8)(i)(B) (proposed § 314.127(h)(1)(i) and (h)(1)(ii)) reflects the statutory language at section 505(j)(3)(H)(i) and (j)(3)(H)(ii) of the act, respectively, and serves different purposes. To illustrate, if FDA concluded that an inactive ingredient in a proposed ANDA product was unsafe, it could refuse to approve the ANDA under § 314.127(a)(8)(i)(A). If the proposed ANDA product involved a combination of inactive ingredients and the combination (as opposed to each inactive ingredient), either by the type or quantity of an inactive ingredient or the manner of formulation of the inactive ingredients into the product, shows that the product was unsafe, the refusal to approve the ANDA would occur under § 314.127(a)(8)(i)(B).

FDA received four comments on proposed § 314.127(h)(2) (now § 314.127(a)(8)(ii)). Under the proposal, FDA would consider a drug product's inactive ingredients or composition to be unsafe and refuse to approve an ANDA if, on the basis of information available to FDA, "there is a reasonable basis to conclude that one or more of the inactive ingredients of the proposed drug or its composition raise serious questions of safety."

75. One comment said FDA must have a valid scientific reason, rather than a "reasonable basis" under proposed § 314.127(h)(2)(i), to conclude that an inactive ingredient raises "serious questions of safety." A second comment would replace the list of examples with a shorter, generalized list of safety questions.

If the reference to "valid scientific reason" is meant to suggest that the agency must have proof that a drug is unsafe before taking action, FDA disagrees with the comment. The preamble to the proposed rule explained how FDA concluded that section 505(j)(3)(H) of the act asuthorizes the agency to refuse to approve an ANDA if there is a reasonable basis to conclude that a drug product's inactive ingredients or composition raises serious questions about drug safety. In brief, section 505(e) of the act permits FDA to withdraw ANDA approval if there is evidence that the drug "is not shown to be safe." FDA can invoke this provision whenever there is a reasonable basis to conclude that a drug is unsafe even if the agency lacks proof that the drug is unsafe (54 FR 28902). In comparison, section 505(j)(3)(H) of the act authorizes FDA to refuse to approve an ANDA if "information submitted in the application or any other information available to the Secretary" shows that the drug's inactive ingredients or composition is unsafe. If FDA construed section 505(j)(3)(H) of the act as requiring proof that a drug product is unsafe before it could act, the agency would be obliged to approve an ANDA and then immediately initiate a proceeding to withdraw approval.

The U.S. Supreme Court has held that, in interpreting the act, it must be given " 'the most harmonious, comprehensive meaning possible' in light of the legislative policy and purpose," and must not " ' impute to Congress a purpose to paralyze with one hand what it sought to promote with the other.' " *Weinberger* v. *Hynson, Westcott and Dunning, Inc.*, 412 U.S. 609, 631–632 (1973) (quoting *Clark* v. *Uebersee Finanz-Korp.*, 332 U.S. 480, 488–489). It would be inconsistent with these principles to interpret section 505(j)(3)(H) of the act as imposing a burden of proof on the agency that would require aproval of potentially unsafe drugs, or require a greater showing that a drug is not safe to disapprove a product than is required to withdraw approval of it. Therefore, FDA is interpreting that section as authorizing disapproval of an ANDA on the same basis as withdrawal under section 505(e)(2) of the act. Thus, an ANDA may be disapproved if there is a reasonable basis to conclude that one of its inactive ingredients or its composition raises serious questions about the drug's safety.

As for deleting the list of examples of changes that raise serious questions of safety, FDA has elected to amend the last sentence in § 314.127(a)(8)(ii)(A) (proposed § 314.127(h)(2)(i)) to read, "Examples of the changes that may raise serious questions of safety include, but are not limited to, the following." This amendment shows that the list of examples is not exhaustive and that the described changes do not automatically raise serious safety concerns that preclude ANDA approval.

The proposed rule listed several examples of changes that raise serious questions of safety. These examples included the "use of a controlled release mechanism never before approved for the drug" (proposed § 314.127(h)(2)(i)(E)) and "a change in composition to include a significantly higher concentration of one or more inactive ingredients than previously used in the drug product" (proposed § 314.127(h)(2)(i)(F)).

76. The third comment asked FDA to delete § 314.127(h)(2)(i)(E) and (h)(2)(i)(F) (now § 314.127(a)(8)(ii)(A)(*5*) and (a)(8)(ii)(B)(*6*)). The comment claimed that the use of a different controlled release mechanism or a change in composition to include a significantly higher concentration of one or more inactive ingredients should not preclude ANDA approval. The comment also suggested revising § 314.127(h)(2)(i)(F) to read, "A change in composition to include levels of an inactive ingredient for which published data may exist showing such levels to be unsafe."

FDA declines to accept the comment. When read in its entirety, proposed § 314.127(h)(2) states that FDA will consider a drug's inactive ingredients or composition to be unsafe and refuse to approve an ANDA if "there is a reasonable basis to conclude that one or more of the inactive ingredients of the proposed drug or its composition raise serious questions of safety." FDA believes that such a reasonable basis may exist in the absence of published data. As the rule and the preamble to the proposed rule note, the examples listed in proposed § 314.127(h)(2)(i)(E) and (h)(2)(i)(F) simply illustrate FDA's experience. (See 54 FR 28903.) Thus, if the proposed drug product uses a delivery or release mechanism that has never been approved for that drug or contains a higher concentration of one or more inactive ingredients, FDA will not automatically refuse to approve the ANDA. Instead, FDA will refuse to approve the ANDA only if there is a reasonable basis to conclude that the change raises serious safety questions.

FDA has, however, revised the wording in the final rule at § 314.127(a)(8)(ii)(A)(*5*) to replace "a controlled release mechanism" with "a delivery or a modified release mechanism." This change reflects the agency's experience with novel delivery or modified release mechanisms and places emphasis on the delivery mechanism or modified release mechanism itself whereas the proposed rule could have been interpreted as focusing concern solely on controlled release mechanisms.

FDA has also revised the final rule at § 314.127(a)(8)(ii)(A)(*6*) to replace "higher concentration" with "greater content." This change recognizes the fact that minutely higher concentrations of one or more inactive ingredients do not always present serious questions of safety. In contrast, a drug that has a greater content of one or more inactive ingredients often presents serious questions of safety.

77. Proposed § 314.127(h)(2)(ii) (now § 314.127(a)(8)(ii)(B)) said FDA would consider an inactive ingredient in, or the composition of, a drug product intended for parenteral use to be unsafe and refuse to approve the ANDA unless "it contains the same inactive ingredients, other than preservatives, buffers, and antioxidants, in the same concentration as the listed drug, and, if it differs from the listed drug in a preservative, buffer, or antioxidant, the application contains sufficient information to demonstrate that the difference does not affect the safety of the drug product." A comment said that requiring information to show that changes in a preservative, buffer, or antioxidant do not affect safety was "unnecessarily excessive" because FDA knows commonly used preservatives, buffers, and antioxidants. The comment suggested revising the provision only to require submission of information on preservatives, buffers, and antioxidants that are not commonly used.

The statute authorizes the Secretary to withhold approval of an ANDA if

information submitted in the application or any other information available shows that "(i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included." (See 21 U.S.C. 355(j)(3)(H).) Thus, under the statute, the inquiry is not whether each preservative, buffer, and antioxidant is commonly used or known; instead, the inquiry is whether the preservatives, buffers, and antioxidants in the proposed drug product are safe under the conditions prescribed, recommended, or suggested in the labeling. Section 314.127(a)(8)(ii)(B) of this final rule reflects this concern, which is particularly acute for parenteral drug products. Therefore, FDA declines to revise the rule as suggested.

Section 314.150—Withdrawal of Approval of an Application or Abbreviated Application

Proposed § 314.150 concerned withdrawals of approvals of an application or abbreviated application under section 505(e) of the act. The proposed rule would permit FDA to withdraw approval of an application or abbreviated application under certain enumerated conditions, such as a finding that an imminent hazard to the public health exists (§ 314.150(a)(1)), or a finding that clinical data or other experience, tests, or scientific data show the drug is safe for use under the conditions of use approved in the application or abbreviated application (§ 314.150(a)(2)(i)).

78. Two comments said FDA should create a new provision authorizing the agency to withdraw an abbreviated application if the abbreviated application holder failed to modify its labeling to match labeling changes in the reference listed drug.

FDA agrees and has revised the rule accordingly. New § 314.150(b)(10) states that the ANDA applicant's failure to maintain drug labeling that is consistent with that of the listed drug may be grounds for withdrawing approval of the abbreviated application. The only exceptions to this withdrawal provision are labeling differences approved in the original ANDA or resulting from a patent issued on the listed drug after approval of the ANDA or from exclusivity accorded to the listed drug after approval. However, as noted in paragraph 39 above, if the agency concludes that a labeling difference resulting from patent protection or exclusivity compromises the safety or effectiveness of the generic drug product for any remaining conditions of use, FDA may withdraw approval of the ANDA under this provision.

Section 314.151—Withdrawal of Approval of an Abbreviated New Drug Application Under Section 505(j)(5) of the Act; Section 314.152—Notice of Withdrawal of Approval of an Application or Abbreviated Application for a New Drug

79. Proposed § 314.151 (concerning withdrawals of approval of ANDA's under 21 U.S.C. 355(j)(5)) did not provide ANDA applicants the opportunity for an oral hearing in the event of a withdrawal. FDA received seven comments claiming that ANDA applicants should have an opportunity for a hearing or an oral hearing when FDA proposes to withdraw approval of an application or abbreviated application. In general, the comments argued that ANDA applicants should have the opportunity for a hearing on due process grounds or to "assure fairness." One comment stated that section 505(e) of the act authorizes hearings whenever the agency proposes to withdraw approval of an application approved under section 505, and, therefore, ANDA holders were entitled to hearings because ANDA's are authorized by section 505(j) of the act. One comment, however, would deny ANDA applicants the opportunity for a hearing because an ANDA "is completely dependent on the continued approval of the reference listed drug" and the ANDA applicant "does not take the place of the listed drug applicant for purposes of exercising the right to protect that drug."

The statute and regulations contemplate withdrawing ANDA approval under two different circumstances. First, if FDA finds the ANDA product unsafe for use, lacks substantial evidence of effectiveness under the conditions of use prescribed, recommended, or suggested in its labeling, contains an untrue statement of material fact, or meets any of the other grounds for withdrawal under section 505(e) of the act, the agency may withdraw approval "after due notice and opportunity for hearing to the applicant" (21 U.S.C. 355(e)). For ANDA products, the regulations pertaining to a withdrawal of approval under section 505(e) of the act are at § 314.150. These regulations, contrary to some of the comments' assertions, do give ANDA holders an opportunity for a hearing on a proposal to withdraw approval of an ANDA to the extent that one or more of the grounds for withdrawal under section 505(e) of the act directly apply to the ANDA product. (See § 314.150 (a) and (b).)

The second situation in which ANDA approval may be withdrawn focuses on withdrawal of the listed drug rather than the ANDA product itself. Under section 505(j)(5) of the act, if the listed drug is withdrawn for safety or effectiveness reasons or any of the grounds listed in section 505(e) of the act, ANDA approval "shall be withdrawn or suspended * * *." The statute does not require FDA to give the ANDA holder an opportunity for a hearing before withdrawing or suspending ANDA approval.

The preamble to the proposed rule discusses this subject in greater detail. (See 54 FR 28904 through 28907.)

Notwithstanding the absence of a statutory requirement for a hearing, some comments claimed that due process requires FDA to give applicants an opportunity for an oral hearing for a proposal to withdraw ANDA approval under section 505(j)(5) of the act. FDA disagrees. As noted in the preamble to the proposed rule, courts have declared a "paper hearing" that provides adequate notice and a genuine opportunity to present one's case to be adequate. (See 54 FR 28904, July 10, 1989, and cases cited therein.) Section 314.151, therefore, gives ANDA holders a paper hearing and, if FDA cannot resolve the issues on the basis of the written submissions, permits FDA to hold a limited oral hearing. (See 21 CFR 314.151(b) and (c)(3).)

FDA believes these procedures are consistent with the statute and provide ANDA applicants adequate due process. Consequently, FDA declines to amend the rule as requested.

Section 314.153—Suspension of Approval of an Abbreviated New Drug Application; Section 314.161—Determination of Reasons for Voluntary Withdrawal of a Listed Drug

Proposed § 314.153(b) contained procedures for suspension of an ANDA when a listed drug is voluntarily withdrawn for safety or effectiveness reasons. The preamble to the proposed rule stated that "if a drug manufacturer withdraws a drug from the market which accounted for significant sales to that manufacturer, and there is no evidence to the contrary, it will be presumed that the withdrawal was for safety or effectiveness reasons" (54 FR 28907). The agency expressed its intent to employ the same presumption in applying proposed § 314.161.

80. FDA received eight comments on proposed §§ 314.153 and 314.161. All eight comments objected to the presumption stated in the preamble, but for different reasons. Many comments listed possible reasons why an NDA holder would voluntarily withdraw a drug for business or economic reasons alone. Some comments said ANDA holders should not have the burden of showing why the NDA holder voluntarily withdrew the reference listed drug. These comments would have FDA determine the reasons for a withdrawal or require the NDA holder to state its reasons for withdrawing the listed drug. Other comments said the presumption might adversely affect an NDA holder in product liability litigation. A minority of comments said the presumption's reference to "significant sales" was too vague and would produce different results between large and small firms; these comments argued that FDA, if it retained the presumption, should examine research and development expenses, percentage of a company's gross revenues, or the product's sales record for the previous year.

As stated in the preamble to the proposed rule, FDA is aware that companies may withdraw a drug from the market for reasons unrelated to the product's safety or effectiveness. (See 54 FR 28907.) The preamble also noted that FDA is not required to determine why a sponsor voluntarily withdrew a listed drug, and, considering the number of drugs withdrawn from the market every year, "it would be a needless expenditure of resources for the agency to determine the reason for each such withdrawal." Id. The comments have not raised any new issues or advanced any compelling justification for changing the presumption. The agency does note, however, that the presumption is a rebuttable one, and adds that the agency will, when the product is a top 200 drug (as reported in the April issue of Pharmacy Times which is based on data obtained from the National Prescription Audit conducted by IMS America, Ltd., Ambler, PA), and in other cases when it deems it to be necessary, contact the sponsor of the listed drug to inquire about the reasons for a voluntary withdrawal. In addition, the regulations do not prohibit NDA holders from disclosing their reasons for withdrawing a drug product from marketing, and FDA would consider that information in determining whether the withdrawal was for safety and effectiveness reasons. FDA would not consider the NDA holder's stated reasons for withdrawing a drug to be determinative because such remarks could be biased. Similarly, if an ANDA applicant can show that the reasons for withdrawal of the listed drug are not relevant to the safety or effectiveness of the ANDA drug product, the agency will not suspend ANDA approval. (See 21 CFR 314.153(b)(6).)

As for the comments suggesting alternatives to "significant sales," FDA agrees that the term may have different meanings to different companies, and will adopt a case-by-case approach when determining whether a product accounted for significant sales.

For these reasons, FDA has retained the presumption without change.

Section 314.160—Approval of an Application or Abbreviated Application for Which Approval Was Previously Refused, Suspended, or Withdrawn; Section 314.162—Removal of a Drug Product from the List; Section 314.200—Notice of Opportunity for Hearing; Notice of Participation and Request for Hearing; Grant or Denial of Hearing

FDA received no comments on these provisions and has finalized them without change.

Section 314.430—Availability for Public Disclosure of Data and Information in an Application or Abbreviated Application

81. FDA received four comments on proposed § 314.430. The proposal simply added the term "abbreviated application" to FDA's preexisting public disclosure policies and did not make any substantive changes to those policies. Two comments asked FDA to release a summary basis of approval (SBA) or permit ANDA sponsors to release their own SBA's when an ANDA is approved.

Section 314.430(e)(2)(ii) permits FDA to make an SBA available for public disclosure after FDA sends an approval letter. Hence, the comment's request to have FDA release an SBA is unnecessary. FDA also declines to amend the rule to permit sponsors to release their own SBA's. The rule pertains only to the release of information by FDA; sponsors are always free to disclose whatever truthful and nonmisleading information they wish about their own products.

82. One comment asked FDA to amend the rule to reveal the "presence" of a pending ANDA without any further identification so applicants could make "a more educated decision" about possible exclusivity.

While the comment has some merit, FDA declines to amend the rule at this time. The agency is reexamining certain aspects of its public disclosure policies, but notes that a suit to declare a patent to be invalid or not infringed by the manufacture, use, or sale of a drug product may suggest that an ANDA for that drug product has been submitted.

83. Another comment would give all NDA holders an opportunity to prevent disclosure of information for which they had previously requested confidentiality.

The act states that safety and effectiveness data submitted in an application under section 505(b) of the act and not previously disclosed to the public, "shall be made available to the public, upon request, unless extraordinary circumstances are shown." (See 21 U.S.C. 355(1).) Thus, the statute clearly favors disclosure of safety and effectiveness data except in limited situations. FDA is reexamining its policies with respect to section 505(1) of the act, and, until it completes its deliberations, declines to amend the rule as requested. FDA will continue its policy of consulting parties before disclosing information where the confidentiality of data and information is uncertain. (See, e.g., 21 CFR 20.45.)

Section 314.440—Addresses for Applications and Abbreviated Applications

FDA received no comments on this provision. However, due to reorganizations within FDA, the agency has revised the addresses to which abbreviated antibiotic application applicants and ANDA applicants are to send documents and correspondence.

Section 320.1—Definitions

Proposed § 320.1 defined "bioequivalence," in part, as "the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study."

84. Six comments argued that § 320.1 should not include nonsystemically absorbed drug products and should not provide mechanisms other than blood level tests for bioequivalence. The comments noted that section 505(j)(7) of the act states that a drug shall be considered to be bioequivalent to a listed drug if, inter alia, "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental

conditions * * *." The comments claimed that this statutory provision precludes FDA from approving ANDA's for nonsystemically absorbed drug products because, the comments argued, the rate and extent of absorption of such products cannot be measured. One comment stated that in vivo bioavailability studies should be done to confirm that drugs not intended to be absorbed are not unintentionally absorbed.

The agency does not agree with the comments' interpretation of the statute. In 1977, FDA issued final regulations establishing the requirements for demonstrating the bioavailability and bioequivalence of drug products approved under both full new drug applications and ANDA's (21 CFR part 320). The definitions of "bioavailability" and "bioequivalence" adopted in those regulations were, in all pertinent respects, identical to the language used in section 505(j)(7) of the act. Although the 1977 regulations and the 1984 amendments to the act, which incorporate in the statutory provision on "bioequivalence" the language of those regulations, refer to "rate and extent of absorption," the 1977 regulations explicitly applies to drugs that are not intended for systemic absorption.

As originally proposed, the regulatory definition of "bioavailability" contained explicit reference to bioavailability studies other than systemic absorption studies. In the 1977 final rule, the Commissioner of Food and Drugs removed the references to the types of studies that can demonstrate bioavailability or bioequivalence as unnecessary and placed descriptions of appropriate studies in §§ 320.23, 320.24, 320.53, and 320.57. At the same time, the Commissioner of Food and Drugs specifically rejected a comment urging the definition of bioavailability to be restricted to products absorbed into the systemic circulation, stating that the concept of bioavailability applies to all drug products. (See 42 FR 1638 at 1639; January 7, 1977.)

All drug products must be absorbed through some physical barrier to reach the site of drug action, even if that absorption involves only dispersion into a body fluid pool or entry into surface cells. It is well established that drugs may be either locally or systemically absorbed, and nothing in the language of the statute requires that the absorption result in transit through cells or to the systemic circulation. Because Congress adopted the language of the 1977 regulations, and because the legislative history contains no evidence that Congress intended to exclude nonsystemically absorbed drugs from the coverage of the ANDA provisions of the 1984 amendments, FDA rejects the interpretation of section 505(j)(7)(B) of the act offered by these comments.

FDA also disagrees that blood levels are always appropriate or necessary measurements of bioequivalence. Bioequivalence can be established by pharmacodynamic measurement as well as by in vitro techniques and bioequivalence studies with clinical endpoints. The preferred method for establishment of bioequivalence, including the need to confirm that drugs not intended to be absorbed are not unintentionally absorbed, is determined on a case-by-case basis, depending on the drug under study.

Section 505(j)(6) of the act directs the Secretary to publish a list of all approved drugs for which ANDA's may be submitted and to state "whether in vitro or in vivo bioequivalence studies, or both such studies, are required * * *" (21 U.S.C. 355(j)(6)). In vitro studies are "test tube" studies intended to simulate drug effects in the human body, and are, by definition, indirect measurements of bioequivalence. Had Congress intended to require only direct measurements of the rate and extent of absorption in the human body, it would not have also permitted in vitro studies to satisfy the bioequivalence requirements. Thus, the statute permits and FDA's longstanding regulations provide for both indirect and direct measurements of bioequivalence applicable to nonsystemically absorbed drug products.

In summary, FDA's inclusion of nonsystemically absorbed drug products and inclusion of mechanisms other than blood level tests to establish the bioequivalence of drug products are consistent with the statute. The final rule therefore describes the types of studies that can be appropriately used to demonstrate bioavailability, and describes the bioavailability studies that are appropriate for nonsystemically absorbed durgs.

85. Proposed § 320.1 (a) and (e) defined "bioavailability" and "bioequivalence" using the phrase "active ingredient or active moiety." One comment proposed that the term "active moiety," which is used in proposed § 320.1 (a) and (e), does not find any statutory support and the regulations should instead use the statutory term "active ingredient." The comment's position was based on two court cases, *Abbott* v. *Young*, and *Glaxo* v. *Quigg*, which addressed the issue of using the term "active ingredient" as provided by statute instead of using the term "active moiety," with respect to the exclusivity provisions of title I and the patent term extension provisions of title II of the 1984 amendments, respectively. The comment stated that the courts concluded that there is a significant difference between the plain meaning of the statutory term "active ingredient" and the use of "active moiety." Equating the two is not permitted absent clear congressional intent. Thus, the comment argued that the term "active moiety" should not be used.

FDA disagrees with the comment. The court cases referred to by the comment are not relevant to FDA's use of the term "active moiety" in 21 CFR part 320. The statutory definition of "bioavailability" (section 505(j)(7)(A) of the act) uses the phrase "active ingredient or therapeutic ingredient," and the language on "bioequivalence" (section 505(j)(7)(B) of the act) uses the phrase "therapeutic ingredient." The agency is not substituting the phrase "active moiety' for the phrase "active ingredient." The phrase "active ingredient" remains in the definition of "bioavailability" in § 320.1(a) as in the statutory definition. The phrase "active ingredient" is not used in the statutory provision on "bioequivalence."

Congress clearly intended a meaning different from "active ingredient" by the term "therapeutic ingredient" or it would not have used both terms. The term "active moiety" refers to the molecule or ion in an active ingredient, excluding those appended portions of the molecule that cause the ingredient to be an ester, or a salt or other noncovalent derivative that is responsible for the physiological or pharmacological action of the ingredient. The agency believes that the term "active moiety" is more appropriate and has substituted this term for the term "therapeutic moiety" or "therapeutic ingredient" in defining the terms "bioavailability" and "bioequivalence."

86. One comment supported the proposed definition in § 320.1(e) of "bioequivalence" and opposed "across the board in vivo testing requirements." The comment asked FDA to "retain an open attitude toward the use of in vitro tests" and to have the regulations "reflect the fact that there are indeed other current and evolving methodologies, such as 'punch bioassays' and 'skin-blanching' tests, that will provide an equal measure of scientific comfort to demonstrate bioequivalence."

The final rule does not impose across-the-board in vivo testing requirements. With respect to drug products that are not included in the classes of drug

products described in § 320.22 for which the submission of evidence obtained in vivo is waived, FDA will consider requests for waiver of evidence obtained from in vivo testing on an individual basis. In addition, when other, more accurate, sensitive, and reproducible testing methods are not available, FDA will accept appropriately designed comparative clinical trials for purposes of demonstrating in vivo bioequivalence. Section 320.24 describes in vivo and in vitro testing approaches in descending order of accuracy, sensitivity, and reproducibility that are acceptable to FDA for determining the bioavailability or bioequivalence of a drug product.

87. The proposed definition of bioequivalence at § 320.1(e) provides that where there is an intentional difference in rate (e.g., in certain controlled release dosage forms), certain pharmaceutical equivalents or alternatives may be considered bioequivalent if there is no significant difference in the extent to which the active ingredient of moiety becomes available at the site of drug action. This applies only if the difference in the rate at which the active ingredient or moiety becomes available at the site of drug action is reflected in the proposed labeling, is not essential to the attainment of effective body drug concentrations, and is considered medically insignificant for the drug.

One comment suggested that the last sentence in § 320.1(e) be amended by replacing the conjunction "and" with "or." The comment also suggested that FDA define an "intentional difference" as one that involves the improvement of patient compliance or the manufacture of a more pharmaceutically elegant dosage form.

FDA declines to revise the definition as suggested by the comment. The use of the conjunction "and" in the regulation is consistent with statutory language in section 505(j)(7)(B)(ii) of the act. FDA also declines to define "intentional difference" as one that involves the improvement of patient compliance or the manufacture of a more pharmaceutically elegant dosage form because there may exist other valid reasons for altering rate, for example, to reduce toxic effects produced by high concentrations of a drug in an immediate release formulation.

88. Proposed § 320.1(e) defines bioequivalence to mean the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives become available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. Several comments asked FDA to clarify the meaning of the phrase "significant difference" in the definition. Two comments understood "significant difference" to mean a "medically significant" or "therapeutically significant" difference. Other comments interpreted the phrase as meaning a statistically significant difference.

The determination of a significant difference requires first a judgment as to what difference in a bioequivalence parameter of interest is medically important and, second, a statistical analysis of data for the parameter to ensure that the difference determined to be important is not likely to be exceeded. Thus, based on clinical experience, the agency has developed statistical criteria for determining the bioequivalence of drug products. For example, there is a presumption that most drug products show no significant difference from the rate and extent of absorption of the listed drug and that the differences are unlikely to be clinically significant in patients when their absorption (AUC and C_{max}) is within 20 percent of the listed drug in normal subjects, and the probability that the results occurred by chance is less than 5 percent ($p<.05$).[1] In other words, unless there is a justification for different limits, the extent of absorption of the generic product must be not less than 80 percent, and not more than 120 percent, of the extent of absorption from the listed or innovator product. However, FDA will reexamine approval criteria for products falling outside the established statistical boundaries when applicants submit to FDA convincing evidence to establish a greater window of bioavailability or bioequivalence.

89. One comment asked FDA to clarify the difference between bioequivalence and therapeutic equivalence for products with intentional rate differences. Another comment argued that to rate some controlled release dosage form drugs as bioequivalent to an immediate release listed drug, but not as therapeutically equivalent, would create two subsets of bioequivalent products—one where products are therapeutically equivalent, and another where products are not therapeutically equivalent, leading to confusion in interchangeability.

Therapeutic equivalence was defined in the Federal Register of January 12, 1979 (44 FR 2932 at 2937). To be rated as therapeutically equivalent, drug products must be pharmaceutical equivalents—i.e., contain identical amounts of the same active drug ingredient in the same dosage form—and meet identical compendia or other applicable standards of identity, strength, quality, and purity; must not present a known or potential bioinequivalence problem (or, if so, must meet an appropriate bioequivalence standard); must be adequately labeled; and must be manufactured in compliance with the regulations governing CGMP's. The agency will approve certain products with intentional rate differences as bioequivalent and rate them as therapeutically equivalent provided that they are pharmaceutical equivalents and the difference in rate at which the active ingredient or moiety becomes available at the site of drug action is intentional, reflected in the proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug (21 CFR 320.1 (e)).

The agency believes that it is appropriate to approve certain controlled release dosage form drug products that are pharmaceutical alternatives, for which bioequivalence can be demonstrated, even though products that are not pharmaceutical equivalents cannot be rated as therapeutically equivalent. The agency's publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the list) does not rate these products as therapeutically equivalent; thus, FDA does not consider them interchangeable. Because pharmaceutical alternatives are listed

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[1] See "Report by the Bioequivalence Task Force on Recommendations from the Bioequivalence Hearing Conducted by the Food and Drug Administration, September 29–October 1, 1986," report dated January 1988 (Ref. 1). "There was consensus at the Hearing that differences of less than 20% in AUC and Cmax between products in normal subjects are unlikely to be clinically significant in patients. * * * Under current review procedures, the 90% confidence interval for the ratio of the test product mean AUC to that of the innovator must lie entirely within the inverval (0.80, 1.20)." (Page 29.)

Attachment five to the Report by the Bioequivalence Task Force states "current practice is to carry out the two one-sided tests at the .05 level of significance."

Attachment ten to the Report by the Bioequivalence Task Force states "For approval in most cases, the generic manufacturer must show that a 90% confidence interval of the difference between the mean response of its product and that of the innovator is within the limits ± 20% of the innovator mean. * * * FDA should use the 90% confidence interval (i.e., two one-sided t-tests each at the .05 level of significance) to evaluate the difference between treatments."

See, also, Schuirmann (Ref. 2 at p. 676), "the common ± 20% criteria" and Nightingale and Morrison (Ref. 3 at p. 1200), "With very few exceptions, experts have concluded that differences of less than 20% in the mean AUC between brand name and generic copies are acceptable."

under separate headings, and because only products rated as equivalent under the same heading are interchangeable, there should be no confusion about their interchangeability.

90. One comment disagreed that a product whose absorption rate is intentionally different from the listed drug's absorption rate can nevertheless be bioequivalent. The comment cited nitroglycerine as a product whose absorption rate is critical to effectiveness. Another comment stated that the rate differences should not need to be intentional for these products to be bioequivalent.

Both the statute and the final rule consider a product with a different rate of absorption than the listed product to be bioequivalent to the listed product only if the difference in rate is (1) intentional, (2) reflected in the labeling, (3) not essential to the attainment of effective body concentrations on chronic use, and (4) considered to be medically insignificant. All four criteria must be met for a product with a different rate of absorption to be considered bioequivalent. Thus, a product cannot be rated as bioequivalent to a listed drug when there is a difference in rate of absorption that is not intended or when the difference in rate of absorption is medically significant.

91. One comment asked that FDA expand by example or therapeutic category the drugs that can differ in rate of absorption and still be bioequivalent.

The agency is unaware of any category of products that can differ in rate of absorption and still be considered bioequivalent. Because an intentional rate difference from the reference product would need to be shown to be medically insignificant, FDA believes that determinations of bioequivalence in such cases would need to be made on a case-by-case basis.

Section 320.21—Requirements for Submission of In Vivo Bioavailability and Bioequivalence Data

Proposed § 320.21 would revise FDA's existing requirements for submitting in vivo bioavailability data to include in vivo bioequivalence data.

92. One comment stated that § 320.21(b), which would require evidence of bioequivalence to be included in an ANDA, contradicts the agency practice of accepting applications containing only bioequivalence protocols.

As stated above at paragraph 28, FDA will only accept complete applications. Incomplete applications will not be accepted. Thus, § 320.21(b) of this rule is consistent with current agency practice.

93. Proposed § 320.21(c) would require any person submitting a supplemental application to include bioavailability or bioequivalence evidence if the supplemental application proposes: (1) A change in the manufacturing process; (2) a labeling change to provide for a new indication, if clinical studies are required to support the new indication, or (3) a labeling change to provide for a new dosage regimen or an additional dosage regimen for a special patient population, if clinical studies are required to support the new or additional dosage regimen. One comment suggested that § 320.21(c)(2) and (c)(3) apply only to supplements to applications submitted under section 505(b) of the act. A second comment recommended that § 320.21(c)(2) and (c)(3) be removed because, the comment declared, bioavailability or bioequivalence data should not be needed in addition to clinical studies.

FDA disagrees with the suggested changes. The regulation at § 320.21(c)(2) and (c)(3) applies to supplements to ANDA's approved under section 505(j) of the act as well as to supplements to NDA's approved under section 505(b). (Because such a supplement to an ANDA would require review of clinical data, FDA would treat it as a submission under section 505(b) of the act.) There are a number of reasons why the agency would want bioavailability or bioequivalence data to be included in a supplement for which clinical studies were being conducted. For example, when a supplement covers a new dosage regimen, the agency is concerned about the possibility of nonlinear kinetics. Likewise, for a new patient population, the agency is concerned about the way the drug is absorbed, distributed, and cleared by the body in the target population. Some supplements for a new labeling indication will be for drug products for which a bioavailability study was never performed. In addition, clinical studies are often not done using the final formulation, and the agency may need bioavailability or bioequivalence information on the final formulation. However, in vivo bioavailability or bioequivalence studies are not always needed, and paragrapohs (a)(2) and (b)(2) in § 320.21 provides for FDA to waive the requirement for in vivo studies based on the submission of adequate information.

94. Proposed § 320.21(g) would, under specific circumstances, require any person holding an approved full or abbreviated application to submit to FDA a supplemental application containing new evidence demonstrating in vivo bioavailability or bioequivalence. One comment asked that the information that would cause FDA to require new evidence demonstrating in vivo bioavailability or bioequivalence be made publicly available and that the source of such information be disclosed.

FDA's regulations governing public information are intended to "make the fullest possible disclosure of records to the public, consistent with the rights of persons in trade secrets and confidential commercial or financial information * * *" (21 CFR 20.20(a)). Publicly disclosable information includes information contained in citizen petitions as well as information submitted as part of an application under section 505(b) of the act. (See 21 CFR 10.20(j); 21 U.S.C. 355(l).) FDA will make every effort possible—consistent with its obligations to preserve certain trade secret and confidential commercial information—to make public any information it receives that would cause the agency to require new in vivo bioavailability or bioequivalence information.

95. One comment said that FDA should require retention of product samples tested for bioequivalence and that samples should be drawn from commercial-sized lots produced on the equipment that will be used to manufacture the marketed product.

FDA agrees in part with the comment. In the **Federal Register** of November 8, 1990 (55 FR 47034), FDA published an interim rule that requires retention of bioavailability and bioequivalence testing samples. The interim rule applies to manufacturers who conduct in-house bioavailability and bioequivalence tests and to facilities conducting such testing under contract for a drug manufacturer. FDA does not agree that bioequivalence studies need necessarily be conducted on commercial-sized lots if certain conditions are met. See Office of Generic Drugs Policy and Procedure Guide 22-90 (September 13, 1990).

Section 320.22—Criteria for Waiver of Evidence of In Vivo Bioavailability or Bioequivalence

Proposed § 320.22 would, among other things, revise the existing criteria for waiving evidence of in vivo bioavailability to include waivers of in vivo bioequivalence, delete automatic waivers of in vivo bioavailability for certain drug products, and remove the list of "bioproblem" drugs.

96. One comment argued that the statute prohibits a waiver of in vivo bioequivalence data. Another comment urged that § 320.22 be revised to waive in vivo bioequivalence requirements for

topically applied preparations and drug products that are oral dosage forms not intended to be absorbed.

Although the statute requires ANDA applicants to provide bioequivalence information (except where the ANDA is being submitted for a change in a listed drug for which a suitability petition has been granted), it does not require that bioequivalence be shown through in vivo methods. For example, section 505(j)(6)(A)(i)(III) of the act requires the Secretary to publish and make available to the public "whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications * * *." If ANDA applicants were limited to in vivo bioequivalence methods, the statutory reference to in vitro methods would be superfluous. FDA, therefore, disagrees with the comment that the statute prohibits waivers of in vivo methods for demonstrating bioequivalence.

FDA has removed the automatic waiver of evidence of in vivo bioavailability for topically applied preparations and oral dosage forms not intended to be absorbed because the agency believes in vivo bioavailability may be required for certain products. Variations in the manufacturing process used by each individual manufacturer may result in differences in the bioavailability of these drug products. While neither topical drug products nor oral dosage forms not intended to be absorbed are listed in the class of products whose bioavailability may be considered self-evident based on other data in the application, applicants of such products may nevertheless request a waiver of the requirements for in vivo data under § 320.22(a). The agency will review each product on a case-by-case basis to determine if an in vivo study is necessary.

97. One comment said the proposed rule would increase duplicative safety and efficacy tests and increase the time and expense of obtaining ANDA's by reverting to "across-the-board" in vivo study requirements. It argued that removing automatic waivers for topical and nonsystemically absorbed drugs would make it nearly impossible for an ANDA applicant to obtain marketing approval and impose new bioavailability standards that exceed the pioneer's testing requirements.

Although § 320.22, as revised, removes the automatic waiver for topical and nonsystemically absorbed oral dosage products, this change does not require applicants to submit evidence of in vivo bioavailability or in vivo bioequivalence in every case. The elimination of the automatic waiver for nonsystemically absorbed oral dosage products simply reflects FDA's view that requests for waiver of in vivo bioavailability and bioequivalence for these products need to be reviewed on a case-by-case basis. While the amendments may well increase the number of in vivo studies required, the regulation does permit applicants to request a waiver of the requirement for the submission of evidence in the form of in vivo bioavailability or bioequivalence data provided the product meets the criteria in § 320.22.

FDA concedes that the burden of showing bioequivalence may sometimes be comparable to, or perhaps even greater than, the pioneer's burden of showing bioavailability. In such cases, FDA believes that the additional data are needed to meet current standards for bioequivalence. FDA also notes that the generic company's burden is not likely to be nearly as great as the pioneer's burden of showing that a drug product is safe and effective for its proposed uses.

98. Under proposed § 320.22(b)(1), FDA would waive the requirement for submission of evidence obtained in vivo demonstrating the bioavailability or bioequivalence of drug products that are solutions for intravenous administration. The proposal stated that the in vivo bioavailability or bioequivalence of these drug products is "self-evident" provided that the drug products contain the same active and inactive ingredients in the same concentration as the listed drug product (21 CFR 320.22(b)(1)(ii)). Proposed § 320.22(c) would provide for a waiver of in vivo data requirement for those "parenteral drug products that are determined to be DESI-effective or that are shown to be identical in both active and inactive ingredient formulation" to a drug product that is currently approved in an NDA (provided that the drug is neither in suspension form, nor phenytoin sodium powder).

On its own initiative, FDA is revising § 320.22(b)(1)(i) to include solutions for all parenteral injections within its scope. As revised, the provision includes, among others, intraocular, intravenous, subcutaneous, intramuscular, intra-arterial, intrathecal, intrasternal, and intraperitoneal solutions intended for parenteral injection. The in vivo bioavailability or bioequivalence of any drug product in that class may be shown without in vivo data if the product contains the same active and inactive ingredients in the same concentration as a drug product that is a subject of an approved full new drug application. Because all parenteral solutions are now included at § 320.22(b)(1)(i), the agency has deleted § 320.22(c), which is no longer needed.

99. Proposed § 320.22(b)(3) would waive the requirement for submission of evidence obtained in vivo demonstrating the bioavailability or bioequivalence of a product that is an oral solution, elixir, syrup, tincture, or similar other solubilized form provided that it contains: (1) An active ingredient in the same concentration and dosage form as a drug product that is the subject of an approved full new drug application; and (2) no inactive ingredient that may significantly affect absorption of the active ingredient or active moiety. One comment asked that ophthalmic and otic solutions be added to the class of products described in § 320.22(b)(3) whose bioavailability or bioequivalence is deemed self-evident.

Although FDA does not believe that the in vivo bioavailability or bioequivalence of otic and ophthalmic solutions can be considered self-evident based on compliance with the criteria described in § 320.22(b)(3), FDA does believe that it can assume the bioavailability or bioequivalence of an ophthalmic or otic product, if the product meets the criteria described in § 320.22(b)(1)(ii), i.e., the product contains the same active and inactive ingredients in the same concentration as a drug product that is the subject of an approved full new drug application. The regulation is revised accordingly.

100. Two comments objected to the requirement in § 320.22(b)(1)(ii) that inactive ingredients be the same as those in the listed drug, arguing that some differences should be allowed and that ANDA applicants do not know the inactive ingredients in the listed drug.

FDA declines to accept the comment. The final rule requires drug products intended for parenteral injection to contain the same inactive ingredients in the same concentrations to obtain a waiver from the in vivo bioavailability or bioequivalence requirement because FDA cannot always predict the consequences of minor changes (e.g., in salt concentration). FDA believes this criterion is important to retain even when the necessary information is not freely available to ANDA applicants. FDA notes that under 21 CFR 201.100(b)(5) drug products for other than oral use must usually list the names of all inactive ingredients except flavorings, perfumes, and color additives. In addition, under 21 CFR 201.100(b)(5)(iii), a drug product, "if it is intended for administration by parenteral injection, (must list) the quantity or proportion of all inactive ingredients, except that ingredients added to adjust the PH or to make the drug isotonic may be declared by name

and a statement of their effect * * *." Thus, ANDA applicants should be able to determine the identity of inactive ingredients for all nonoral dosage forms and the quantity or proportion of inactive ingredients for many drug products, including all parenterals. In many other cases, the identity and quantity of inactive ingredients will be voluntarily disclosed on the listed drug's lable or otherwise ascertainable.

101. Proposed § 320.22(b)(3)(i) stated the conditions under which the bioavailability or bioequivalence of oral solutions, elixirs, syrups, tinctures, or similar products could be considered self-evident. One comment asked that § 320.22(b)(3)(i) be revised to include solutions for application to the skin.

The agency agrees that the in vivo bioavailability or bioequivalence of a solution for application to the skin may be considered self-evident, provided that it has the same active ingredients in the same concentration as the listed drug and no inactive ingredient or change in formulation that may significantly affect absorption of the active drug ingredient or active moiety. Therefore, the regulation at § 320.22(b)(3)(i) has been revised to include solutions for application to the skin. On its own initiative, FDA is revising § 320.22(b)(3)(iii) to make clear that the waiver in that section is conditioned on the applicant making no change in product formulation, including deletion of an inactive ingredient, that may significantly affect the absorption of the active drug ingredient or active moiety.

102. Existing § 320.22(d)(5) waives the requirement for the submission of evidence obtained in vivo demonstrating the bioavailability of a drug product if the product contains the same active drug ingredient and is in the same strength and dosage form as a drug product that is the subject of an approved full or abbreviated new drug application, and both products meet an appropriate in vitro test. FDA proposed to remove this provision, stating that there was no evidence to show that in vitro data alone are regularly sufficient to assure bioequivalence. Three comments asked that existing § 320.22(d)(5) be retained. One comment contended that FDA had little evidence to show that in vitro data alone are not sufficient for the same product manufactured by the same sponsor.

FDA rejects these comments. The burden of showing that a new product is bioavailable or bioequivalent rests with the applicant. In general, the submission of in vivo data is required to support a new product unless there is a known in vivo/in vitro correlation, in which case in vitro data alone may be sufficient. Section 320.22(d) of this final rule lists certain classes of drug products whose bioavailability or bioequivalence may be demonstrated by evidence obtained in vitro in lieu of in vivo. (In addition, FDA continues to waive in vivo data for certain drugs determined to be effective for at least one indication under the DESI program.) As FDA has no evidence to show that in vitro data alone are regularly sufficient to support the bioequivalence of any other drug classes, the agency believes that it is inappropriate to retain existing § 320.22(d)(5). Section 320.22(d)(5) is, therefore, removed.

103. One comment urged that existing § 320.22(d)(5) be retained as a mechanism for waiving in vivo data requirements for minor formulation changes, i.e., changes in colors or flavor. The comment stated that some FDA review divisions require new applications for products that contain a new flavor or color, and concluded that these newly formulated products are not eligible for the waivers described in proposed § 320.22(e)(4).

The comment is incorrect in assuming that products that are reformulated to contain a new flavor, color, or preservative are ineligible for waiver under proposed § 320.20(e)(4) (§ 320.20(d)(4) in this final rule). Such new formulations are eligible for waiver whether they are covered by a new application or by a supplement to an approved application.

104. Proposed § 320.22(e)(2) (§ 320.22(d)(2) in this final rule) would waive the requirement for the submission of in vivo bioavailability evidence if the drug product "is in the same dosage form, but in a different strength, and is proportionally similar in its active and inactive ingredients to another drug product for which the same manufacturer has obtained approval" and the bioavailability of the other drug product has been demonstrated, both drug products meet an appropriate in vitro test approved by FDA, and the applicant submits evidence showing that both drug products are proportionally similar in their active and inactive ingredients. One comment suggested that the agency revise § 320.22(e)(2) to include all dosage forms, including extended release dosage forms. A second comment asked FDA to extend the waiver to extended release capsules whose active ingredients are beaded materials.

The agency never intended to include extended release dosage forms, and has modified § 320.22(d)(2) to so state. The agency disagrees that it would be appropriate to grant waivers to all extended release dosage forms or to all extended release capsules whose active ingredients are beaded materials because the current state of science and technology does not always permit meaningful correlations between in vitro dissolution rates and the rate and extent of in vivo bioavailability for these products. FDA believes that waivers may be appropriate under some circumstances for certain beaded extended release dosage forms. Waivers are ordinarily granted for certain beaded dosage forms, where bioavailability has already been established and the only difference between the reference product and the drug under study is not in the type of bead, but in the quantity of beads. However, waivers will not be granted for beaded dosage forms with nonlinear kinetics because differences of minor therapeutic consequence at lower dose could become greatly exaggerated at higher doses. FDA will consider waiver requests for such products on an individual basis.

105. Proposed § 320.22(g) would permit FDA to require in vivo bioavailability or bioequivalence data if it determines that any difference between the drug product and a listed drug may affect the bioavailability or bioequivalence of the drug product. One comment asked that § 320.22(g) not be used unfairly by pioneer companies to remove generic applicants from the market by bombarding the agency with small bioequivalence changes.

This provision, renumbered § 320.22(f), if not intended and would not be implemented to give unfair marketing advantage to any particular manufacturers. Rather, it permits FDA to impose additional requirements to ensure the continued bioavailability or bioequivalence of a drug product.

Section 320.23—Basis for Demonstrating in Vivo Bioavailability or Bioequivalence

The proposed amendments to § 320.23 would, among other things: (1) Permit applicants whose drug products are not intended to be absorbed into the bloodstream to demonstrate bioavailability by measuring the rate and extent to which the active ingredient or active moiety was absorbed and became available at the site of drug action (§ 320.23(a)(1)); (2) state that statistical techniques used shall be of sufficient sensitivity to detect differences in rate and extent of absorption that are not attributable to subject variability (§ 320.23(a)(2)); (3) rephrase the conditions under which a drug product whose rate of absorption

differs from the reference listed drug can be considered bioavailable (§ 320.23(a)(3)); and (4) declare two drug products to be bioequivalent if they are pharmaceutical equivalents or pharmaceutical alternatives whose rate and extent of absorption do not show a significant difference when administered at the same molar dose of the active moiety under similar experimental conditions, either single dose or multiple dose (§ 320.23(b)).

106. One comment stated that proposed language in § 320.23(a)(2) on "differences in rate * * * of absorption" is ambiguous. The comment said the phrase could be interpreted to mean either differences in the "first-order micro-rate constant for absorption," or, alternatively, maximum concentration, C_{max}, and time to maximum concentration, T_{max}.

The comment correctly points out that the regulation does not specify how absorption rate should be measured. Because drug product parameters may vary, absorption parameters are determined based on the nature of the drug being evaluated.

Section 320.24—Types of Evidence to Establish Bioavailability or Bioequivalence

107. One comment asked that § 320.24 require that an applicant submitting an ANDA for a drug that has a significant difference in a pharmacodynamic parameter that is correlated with safety or therapeutic effect demonstrate that the difference is not clinically significant. The comment also asked that § 320.24 be revised to state FDA's willingness to accept in support of an ANDA pharmacodynamic evidence in lieu of pharmacokinetic profiles when one or more pharmacodynamic parameters correlate with a drug's therapeutic effect.

The ANDA process is intended to provide a rapid and efficient route for generic drug approval. Section 505(j)(7) of the act requires that FDA find a generic drug product to be bioequivalent to the reference listed drug if differences in their rates and extents of drug absorption fall within predetermined statistical limits.

Standards for determining bioequivalence for a product are intended to reflect the nature of the therapeutic response for that product. Once the therapeutic index has been determined, the equivalence of a product's therapeutic response can be measured via plasma drug concentrations, which are generally believed to provide a precise and accurate reflection of product performance. It is highly unlikely that a clinically significant difference in product safety and efficacy will exist for a product that meets an applicable bioequivalence standard. However, should postmarketing surveillance or other information suggest the possibility of therapeutic inequivalence, the approval criteria for that drug entity would be reevaluated.

In general, for systemically absorbed drugs, blood level profiles are a more sensitive index of rate and extent of drug delivery than pharmacodynamic measures. Therefore, except for cases where the agency has indicated otherwise, when blood levels of a drug are measurable, product bioavailability and bioequivalence will be based on pharmacokinetic rather than pharmacodynamic response.

108. Proposed § 320.24(a) stated that applicants should conduct bioavailability or bioequivalence studies "using the most accurate, sensitive, and reproducible approach * * *." One comment suggested that proposed § 320.24(a) be revised to state that applicants who have begun bioequivalence testing under an FDA guidance document would not have to recommence their studies if FDA's guidance changes in the interim.

FDA declines to adopt the comment. Generally, the agency will not ask an applicant to recommence a study that is conducted under an FDA guidance document. However, if new information suggests the need to reconsider agency guidance on study design, the agency will not be bound by that previous guidance. Therefore, under some important circumstances, it may be necessary for an applicant to recommence a study.

109. Proposed § 320.24(b) lists tests in descending order of accuracy, sensitivity, and reproducibility that are acceptable approaches for establishing the bioavailability and bioequivalence of a drug product. On its own initiative, the agency has added to the list of acceptable tests "currently available in vitro tests that ensure human in vivo bioavailability." The addition is intended for drug products determined to be effective under DESI for at least one indication that contain no active ingredients regarded as presenting either actual or potential bioequivalence problems or drug quality or standards issues. These products are coded "AA" in the list of "Approved Drug Products with Therapeutic Equivalence Evaluations." The agency has created new § 320.24(b)(5) to list these in vitro tests, and has renumbered proposed § 320.24(b)(5) as § 320.24(b)(6).

110. One comment questioned whether the three tests listed in § 320.24(b)(1) are themselves listed in descending order of accuracy, sensitivity, and reproducibility. The comment suggested that FDA renumber the approaches to make clear its intent.

The approaches in § 320.24(b)(1) are listed in descending order of accuracy, sensitivity, and reproducibility. This means that the approach under § 320.24(b)(1), is preferable to §320.24(b)(1)(ii), as the comment suggested. The agency believes the regulatory language clearly captures the agency's intent, and does not believe that renumbering the approaches is needed. The comment is therefore rejected.

111. Under proposed § 320.24(b)(1), one approach for demonstrating bioavailability or bioequivalence would be through "an in vivo test in humans in which the concentration of the active ingredient or active moiety and its active metabolites, in whole blood, plasma, serum, or other appropriate biological fluid is measured as a function of time." One comment contended that measurement of active metabolites in an in vivo test should be the exception rather than the rule, and that measurement of metabolites should not be required where the activity of the metabolite is not well documented.

In general, the determination of whether a metabolite would be used in the assessment of a product's bioavailability or bioequivalence is dependent upon the pharmacokinetic characteristics of the drug (e.g., product input function, rate of metabolite formation, and half-lives of the various species). Section 320.24(b) has been revised to make clear that measurement of active metabolites will only be required when appropriate.

112. Two comments objected to the inclusion in the list of approaches to demonstrate the bioavailability or bioequivalence of a product of "well-controlled clinical trials that establish the safety and effectiveness of the product" (§ 320.24(b)(4)). The comments argued that clinical efficacy or safety trials to demonstrate bioequivalence are not bioequivalence determinations under the statute. The comments suggested that FDA should treat as a 505(b) application any ANDA application whose bioequivalency is based on clinical safety and effectiveness data.

As stated elsewhere in this document, the statute does not restrict applicants to a specific method for demonstrating bioequivalence. The preexisting regulations at 21 CFR 320.57 permitted applicants to demonstrate bioavailability and bioequivalence

through well-controlled clinical trials. The final rule retains this provision in § 320.24(b)(4). The measurement of clinical endpoints may thus be an acceptable approach for establishing bioequivalence for purposes of ANDA approval. The fact that clinical trial data are submitted to demonstrate bioequivalence does not therefore force FDA to convert an application to a section 505(b) application.

113. Proposed § 320.24(b)(4) would permit an applicant to determine a product's in vivo bioavailability or bioequivalence through well-controlled clinical trials or comparative clinical trials provided that analytical methods "cannot be developed" to determine that product's bioavailability or bioequivalence through the tests listed in proposed § 320.24(b)(1), (b)(2), or (b)(3). The comment urged that FDA replace the phrase "cannot be developed" with "have not been developed."

The agency declines to accept the comment because it believes that well-controlled clinical trials or comparative clinical trials should be used only when analytical methods cannot be developed using current technology. To allow clinical trials when such methods have not been developed would encourage their use in situations where technology exists, but an applicant prefers not to develop the analytical methods.

Section 320.30—Inquiries to FDA and FDA Review of Protocols

Proposed § 320.30 strongly recommends that persons planning to conduct a bioavailability or bioequivalence study submit proposed protocols to FDA for review before conducting the study. The proposed regulation also provided addresses for general inquiries on in vivo bioavailability and bioequivalence requirements.

114. Two comments suggest that the regulation be revised to require FDA to review proposed protocols. Two other comments asked that, to ensure timely review, the regulation specify a time period in which FDA must respond to requests for review of a protocol.

The agency will review proposed protocols as expeditiously as its resources and other agency demands permit. However, due to limited resources and an inability to predict the volume of submissions it will receive, the agency cannot commit itself to reviewing regularly all protocols nor will FDA specify a time limit for conducting reviews.

115. Proposed § 320.30(b)(2) would have FDA offer advice with respect to whether the reference material to be used in a proposed bioavailability or bioequivalence protocol is appropriate. One comment asked that, wher there are two approved innovator products that are not bioequivalent to each other, FDA allow either to be the reference standard.

As noted in the preamble to the proposed rule (54 FR 28872 at 28880), FDA intends to select reference listed drugs, which will be the reference standards for bioequivalence determinations. FDA will identify in future editions of the publication "Approved Drug Products with Therapeutic Equivalence Evaluations" the reference listed drug. By designating a single reference listed drug against which all generic versions must be shown to be bioequivalent, FDA hopes to avoid significant variations among generically quivalent drug products. Also, as stated previously, if an applicant believes that there are sound reasons for designating another drug as a reference listed drug, it should consult FDA.

Section 320.31—Applicability of Requirements Regarding an "Investigational New Drug Application"

Proposed § 320.31 listed the types of bioavailability and bioequivalence studies for which an investigational new drug application (IND) would be required. Proposed § 320.31(a)(3) would require an IND if the in vivo bioavailability or bioequivalence study involved a cytotoxic drug product.

116. Two comments asked FDA to justify requiring IND's for cytotoxic products and for multiple-dose studies on controlled release products when no single-dose studies have been completed.

FDA believes that IND's are appropriate in these cases because of the potential risks to study participants through dose dumping or other toxic effects. FDA has 30 days to review and respond to an IND to determine potential safety problems and to assure effects that could threaten the safety of the subject participating in the study.

Section 320.51—Procedures for Establishing or Amending a Bioequivalence Requirement

117. The proposed rule proposed to remove 21 CFR 320.51, which sets forth procedurs for establishing or amending a bioequivalence requirement. One comment asked that § 320.51 not be removed because it requires FDA to use notice and comment rulemaking to develop or amend a bioequivalence requirement.

Because the 1984 amendments require that any new generic drug products be demonstrated to be bioequivalent to the reference listed drug (unless it is the subject of an approved ANDA suitaiblity petition), additional authority to impose bioequivalence requirements with respect to such products is not needed. However, on its own initiative, the agency has decided not to remove § 320.51 because it establishes a procedure to impose bioequivalence requirements on other classes of drug products not covered by the bioequivalence requirements in the 1984 amendments, including drug products not subject to premarket approval and drug products whose new drug status is not yet determined. In this final rule, § 320.51 has been redesignated and revised as § 320.32.

IV. Economic Assessment

FDA has considered the economic impact of this regulation which clarifies and facilitates the implementation of Public Law 98–417. Title I of Public Law 98–417 eliminated unnecessary regulatory barriers for generic drug products and has resulted in generic competition on many important post-1962 drugs. Generic drug sales account for a significant portion of total prescription drug sales, and many of these sales would not have occurred in the absence of Public Law 98–417.

Prior to the implementation of title I of Public Law 98–417, in order to market a generic post-1962 drug product, drug sponsors were required to duplicate the innovator's safety and efficacy testing and to submit a "duplicate" NDA. Under title I, sponsors no longer incur duplicate testing costs and are able to market generic products after submitting and gaining approval for an ANDA which does not include the duplicate testing requirement. The costs associated with preparing and submitting an ANDA are significantly lower than the costs for submitting duplicate NDA's for the same products.

The benefits of these implementing regulations for title I are twofold: (1) Savings to consumers who purchase generic post-1962 prescription drug products, and (2) savings to sponsors of generic drug products who submit ANDA's to the agency in order to gain approval to market their products. The consumer savings are the result of the increased availability of lower-priced generic drug products. As new generic products are made available annually (as their patents expire and generic drug products enter the marketplace) the savings to consumers should reach several billion dollars annually over the next 5 to 10 years. The savings to sponsors will vary depending on the

number of applications submitted annually. Small businesses will also be favorably affected because the barriers to market entry have been lowered thereby allowing these firms to enter the generic drug market without incurring duplicate safety and efficacy testing costs. Consequently, FDA concludes the benefits of these regulations implementing title I far exceed the costs. FDA also believes it has streamlined the ANDA process as much as possible thus minimizing the costs and maximizing the net benefits.

The regulatory framework for processing ANDA's under section 505(j) of the act has been in existence since the enactment of the Drug Price Competition and Patent Term Restoration Act in 1984. Thus, most required procedures and their associated economic consequences have been in effect since that time. This rule simply clarifies and facilitates the implementation of the act and will not affect the pace or magnitude of these impacts. Therefore, FDA concludes that this rule is not a "major rule" as defined by Executive Order 12291 and does not require a regulatory impact analysis. Similarly, the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities, and therefore does not require a regulatory flexibility analysis under the Regulatory Flexibility Act of 1980 (Pub. L. 96–354).

V. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1980

This final rule contains information collections which have been submitted for approval to the Office of Management and Budget under the Paperwork Reduction Act of 1980. The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Abbreviated New Drug Application Regulations.

Description: The information requirements collect information from persons who must obtain FDA approval prior to marketing generic copies of previously approved drugs. These persons must submit information in the form of applications, notices, and certifications. FDA will use the information submitted to determine whether the proposed generic drug is eligible for consideration, under what provisions an application would be considered, and whether the proposed drug is identical to the pioneer drug it purports to copy.

Description of Respondents: Businesses.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Section	Annual number of respondents	Annual frequency	Average burden per response	Annual burden hours
314.50(g)	1	1	1 hour	1
314.50(i)	8	1	2 hours	16
314.50(j)	50	1	2 hours	100
314.54	10	1	80 hours	800
314.80, 310.305	40	1	8 hours	320
314.81	700	1	10 min	119
314.93	82	1	10 hours	820
314.94	850	1	160 hours	136,000
314.110	10	1	40 hours	400
314.122, 314.161	1	1	10 hours	10
Total				138,586

There were no comments received on the Paperwork Reduction Act clearance submission or on the burden estimates. Therefore, no changes have been made to these burden estimates. However, the final rule does not finalize the provisions of the proposed rule on patent certification and market exclusivity. The agency has not included those estimates in the final rule.

VII. References

The following information has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. "Report by the Bioequivalence Task Force on Recommendations from the Bioequivalence Hearing Conducted by the Food and Drug Administration, September 29–October 1, 1986," January 1988.

2. Schuirmann, D. J., "A Comparison of the Two One-Sided Tests Procedure and the Power Approach for Assessing the Equivalence of Average Bioavailability," Journal of Pharmacokinetics and Biopharmaceutics, 15:6:657, 1987.

3. Nightingale, S., and J. Morrison, "Generic Drugs and the Prescribing Physician," Journal of the American Medical Association, 4:258:9:1200, 1987.

4. Skelly, J. P. et al., "Workshop Report: In Vitro and In Vivo Testing and Correlations for Oral Controlled/Modified-Release Dosage Forms," Pharmaceutical Research, 7:975–982, 1990.

List of Subjects

21 CFR Part 2

Administrative practice and procedure, Cosmetics, Drugs, Foods.

21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

21 CFR Part 10

Administrative practice and procedure, News media.

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 320

Drugs, Reporting and recordkeeping requirements.

21 CFR Part 433

Antibiotics, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 2, 5, 10, 310, 314, 320, and 433 are amended as follows:

PART 2—GENERAL ADMINISTRATIVE RULINGS AND DECISIONS

1. The authority citation for 21 CFR part 2 continues to read as follows:

Authority: Secs. 201, 301, 305, 402, 408, 409, 501, 502, 505, 507, 512, 601, 701, 702, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 335, 342, 346a, 348, 351, 352, 355, 357, 360b, 361, 371, 372, 374); 15 U.S.C. 402, 409.

2. Section 2.125 is amended by revising the introductory text of paragraph (h)(2) to read as follows:

§ 2.125 Use of chlorofluorocarbon propellants in self-pressurized containers.

* * * * *

(h) * * *

(2) An abbreviated new drug application conforming to § 314.94 of this chapter is acceptable in lieu of a full new drug application for any product included in the classes of products in paragraph (e) of this section if the product is one that is described under § 314.92 of this chapter. A finding has been made that an abbreviated new drug application may be submitted for the following products included in the classes of products listed in paragraph (e) of this section:

* * * * *

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

3. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 21 U.S.C. 41–50, 61–63, 141–149, 467f, 679(b), 801–886, 1031–1309; secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 361, 362, 1701–1706, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1); 42 U.S.C 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11490, 11921, and 12591.

§ 5.80 [Amended]

4. Section 5.80 *Approval of new drug applications and their supplements* is amended in the introductory text of paragraph (c)(1) and paragraph (c)(2)(i) by removing "314.55, and 314.70" and replacing them with "314.70, and 314.94".

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

5. The authority citation for 21 CFR part 10 continues to read as follows:

Authority: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–393); 21 U.S.C. 41–50, 141–149, 467f, 679, 821, 1034, secs. 2, 351, 354–360F, 361 of the Public Health Service Act (42 U.S.C. 201, 262, 263b–263n, 264); secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 5 U.S.C. 551–558, 701–706; 28 U.S.C. 2112.

6. Section 10.30 is amended by revising the introductory text of paragraph (e)(2) and by adding a new paragraph (e)(4) to read as follows:

§ 10.30 Citizen petition.

* * * * *

(e) * * *

(2) Except as provided in paragraph (e)(4) of this section, the Commissioner shall furnish a response to each petitioner within 180 days of receipt of the petition. The response will either:

* * * * *

(4) The Commissioner shall furnish a response to each petitioner within 90 days of receipt of a petition filed under section 505(j)(2)(C) of the act. The response will either approve or disapprove the petition. Agency action on a petition shall be governed by § 314.93 of this chapter.

* * * * *

7. Section 10.45 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 10.45 Court review of final administrative action; exhaustion of administrative remedies.

* * * * *

(d) The Commissioner's final decision constitutes final agency action (reviewable in the courts under 5 U.S.C. 701 *et seq.* and, where appropriate, 28 U.S.C. 2201) on a petition submitted under § 10.25(a), on a petition for reconsideration submitted under § 10.33, on a petition for stay of action submitted under § 10.35, on an advisory opinion issued under § 10.85, on a guideline issued under § 10.90, on a matter involving administrative action which is the subject of an opportunity for a hearing under § 16.1(b) of this chapter, or on the issuance of a final regulation published in accordance with § 10.40, except that the agency's response to a petition filed under section 505(j)(2)(C) of the act and § 314.93 of this chapter will not constitute final agency action until any petition for reconsideration submitted by the petitioner is acted on by the Commissioner.

* * * * *

PART 310—NEW DRUGS

8. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: Secs 201, 301, 501, 502, 503, 505, 506, 507, 512–516, 520, 601(a), 701, 704, 705, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b–360f, 360j, 361(a), 371, 374, 375, 376); secs. 215, 301, 302(a), 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b–263n).

9. Section 310.305 is amended by revising paragraph (a), by removing the word "significant" in paragraph (b)(2), by revising the first sentence in paragraph (c)(4), and in paragraph (d)(1) by removing the words "(Drug Experience Report)" and replacing them with "(Adverse Reaction Report)" to read as follows:

§ 310.305 Records and reports concerning adverse drug experiences on marketed prescription drugs for human use without approved new drug applications.

(a) *Scope.* FDA is requiring manufacturers, packers, and distributors of marketed prescription drug products that are not the subject of an approved new drug or abbreviated new drug application to establish and maintain records and make reports to FDA of:

(1) All serious, unexpected adverse drug experiences associated with the use of their drug products;

(2) Any significant increase in the frequency of a serious, expected adverse drug experience; and

(3) Any significant increase in the frequency of therapeutic failure (lack of effect).

These reports will enable FDA to protect the public health by helping to monitor the safety of marketed drug products and to ensure that these drug products are not adulterated or misbranded.

* * * * *

(c) * * *

(4) Each person identified in paragraph (c)(1) of this section shall review periodically (at least once each year) the frequency of reports of adverse drug experiences that are both serious and expected and reports of therapeutic failure (lack of effect), received or otherwise obtained, and report any significant increase in frequency as soon as possible but in any case within 15 working days of determining that a

significant increase in frequency exists. * * *

* * * * *

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG

10. Part 314 is amended by redesignating existing Subparts C, D, E, and F as subparts D, E, F, and G, respectively, by adding new subpart C, consisting of §§ 314.92 through 314.99, by revising the table of contents with the authority citation continuing to read as follows:

Subpart A—General Provisions

Sec.
314.1 Scope of this part.
314.2 Purpose.
314.3 Definitions.

Subpart B—Applications

314.50 Content and format of an application.
314.54 Procedure for submission of an application requiring investigations for approval of a new indication for, or other change from, a listed drug.
314.60 Amendments to an unapproved application.
314.65 Withdrawal by the applicant of an unapproved application.
314.70 Supplements and other changes to an approved application.
314.71 Procedures for submission of a supplement to an approved application.
314.72 Change in ownership of an application.
314.80 Postmarketing reporting of adverse drug experiences.
314.81 Other postmarketing reports.
314.90 Waivers.

Subpart C—Abbreviated Applications

314.92 Drug products for which abbreviated applications may be submitted.
314.93 Petition to request a change from a listed drug.
314.94 Content and format of an abbreviated application.
314.96 Amendments to an unapproved abbreviated application.
314.97 Supplements and other changes to an approved abbreviated application.
314.98 Postmarketing reports.
314.99 Other responsibilities of an applicant of an abbreviated application.

Subpart D—FDA Action on Applications and Abbreviated Applications

314.100 Timeframes for reviewing applications and abbreviated applications.
314.101 Filing an application and an abbreviated antibiotic application and receiving an abbreviated new drug application.
314.102 Communications between FDA and applicants.
314.103 Dispute resolution.
314.104 Drugs with potential for abuse.
314.105 Approval of an application and an abbreviated application.
314.106 Foreign data.
314.110 Approvable letter to the applicant.
314.120 Not approvable letter to the applicant.
314.122 Submitting an abbreviated application for, or a 505(j)(2)(C) petition that relies on, a listed drug that is no longer marketed.
314.125 Refusal to approve and application or abbreviated antibiotic application.
314.126 Adequate and well-controlled studies.
314.127 Refusal to approve an abbreviated new drug application.
314.150 Withdrawal of approval of an application or abbreviated application.
314.151 Withdrawal of approval of an abbreviated new drug application under section 505(j)(5) of the act.
314.152 Notice of withdrawal of approval of an application or abbreviated application for a new drug.
314.153 Suspension of approval of an abbreviated new drug application.
314.160 Approval of an application or abbreviated application for which approval was previously refused, suspended, or withdrawn.
314.161 Determination of reasons for voluntary withdrawal of a listed drug.
314.162 Removal of a drug product from the list.
314.170 Adulteration and misbranding of an approved drug.

Subpart E—Hearing Procedures for New Drugs

314.200 Notice of opportunity for hearing; notice of participation and request for hearing; grant or denial of hearing.
314.201 Procedure for hearings.
314.235 Judicial review.

Subpart F—Administrative Procedures for Antibiotics

314.300 Procedure for the issuance, amendment, or repeal of regulations.

Subpart G—Miscellaneous Provisions

314.410 Imports and exports of new drugs and antibiotics.
314.420 Drug master files.
314.430 Availability for public disclosure of data and information in an application or abbreviated application.
314.440 Addresses for applications and abbreviated applications.
314.445 Guidelines.

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371, 376).

§ 314.1 [Amended]

11. Section 314.1 Scope of this part is amended in paragraphs (a)(1) and (a)(2) by adding the phrase "or abbreviated application" after the word "application".

12. Section 314.3 is amended by revising paragraph (b) to read as follows:

§ 314.3 Definitions.

* * * * *

(b) The following definitions of terms apply to this part:

Abbreviated application means the application described under § 314.94, including all amendments and supplements to the application. "Abbreviated application" applies to both an abbreviated new drug application and an abbreviated antibiotic application.

Act means the Federal Food, Drug, and Cosmetic Act (sections 201–901 (21 U.S.C. 301–392)).

Applicant means any person who submits an application or abbreviated application or an amendment or supplement to them under this part to obtain FDA approval of a new drug or an antibiotic drug and any person who owns an approved application or abbreviated application.

Application means the application described under § 314.50, including all amendements and supplements to the application.

505(b)(2) Application means an application submitted under section 505(b)(1) of the act for a drug for which the investigations described in section 505(b)(1)(A) of the act and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

Approvable letter means a written communication to an applicant from FDA stating that the agency will approve the application or abbreviated application if specific additional information or material is submitted or specific conditions are met. An approvable letter does not constitute approval of any part of an application or abbreviated application and does not permit marketing of the drug that is the subject of the application or abbreviated application.

Approval letter means a written communication to an applicant from FDA approving an application or an abbreviated application.

Drug product means a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.

Drug substance means an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of

the human body, but does not include intermediates use in the synthesis of such ingredient.

FDA means the Food and Drug Administration.

Listed drug means a new drug product that has an effective approval under section 505(c) of the act for safety and effectiveness or under section 505(j) of the act, which has not been withdrawn or suspended under section 505(e)(1) through (e)(5) or (j)(5) of the act, and which has not been withdrawn from sale for what FDA has determined are reasons of safety or effectiveness. Listed drug status is evidenced by the drug product's identification as a drug with an effective approval in the current edition of FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (the list) or any current supplement thereto, as a drug with an effective approval. A drug product is deemed to be a listed drug on the date of effective approval of the application or abbreviated application for that drug product.

Not approvable letter means a written communication to an applicant from FDA stating that the agency does not consider the application or abbreviated application approvable because one or more deficiencies in the application or abbreviated application preclude the agency from approving it.

Reference listed drug means the listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its abbreviated application.

Right of reference or use means the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval of an application, including the ability to make available the underlying raw data from the investigation for FDA audit, if necessary.

The list means the list of drug products with effective approvals published in the current edition of FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations" and any current supplement to the publication.

13. Section 314.50 is amended by revising the first and fifth sentences in the introductory paragraph, paragraph (a)(2), and the second sentence in paragraph (c)(1), and by adding new paragraph (g)(3) to read as follows:

§ 314.50 Content and format of an application.

Applications and supplements to approved applications are required to be submitted in the form and contain the information, as appropriate for the particular submission, required under this section. * * * These include an application of the type described in section 505(b)(2) of the act, an amendment, and a supplement. * * *

(a) * * *

(2) A statement whether the submission is an original submission, a 505(b)(2) application, a resubmission, or a supplement to an application under § 314.70.

* * * * *

(c) *Summary.* (1) * * * The summary is not required for supplements under § 314.70. * * *

* * * * *

(g) * * *

(3) If an applicant who submits a new drug application under section 505(b) of the act obtains a "right of reference or use," as defined under § 314.3(b), to an investigation described in clause (A) of section 505(b)(1) of the act, the applicant shall include in its application a written statement signed by the owner of the data from each such investigation that the applicant may rely on in support of the approval of its application, and provide FDA access to, the underlying raw data that provide the basis for the report of the investigation submitted in its application.

* * * * *

14. New § 314.54 is added to read as follows:

§ 314.54 Procedure for submission of an application requiring investigations for approval of a new indication for, or other change from, a listed drug.

(a) The act does not permit approval of an abbreviated new drug application for a new indication, nor does it permit approval of other changes in a listed drug if investigations, other than bioavailability or bioequivalence studies, are essential to the approval of the change. Any person seeking approval of a drug product that represents a modification of a listed drug (e.g., a new indication or new dosage form) and for which investigations, other than bioavailability or bioequivalence studies, are essential to the approval of the changes may, except as provided in paragraph (b) of this section, submit a 505(b)(2) application. This application need contain only that information needed to support the modification(s) of the listed drug.

(1) The applicant shall submit a complete archival copy of the application that contains the following:

(i) The information required under § 314.50 (a), (b), (c), (d)(1) and (d)(3), (e), and (g).

(ii) The information required under § 314.50 (d)(2), (d)(4) (if an anti-infective drug), (d)(5), (d)(6), and (f) as needed to support the safety and effectiveness of the drug product.

(iii) Identification of the listed drug for which FDA has made a finding of safety and effectiveness and on which finding the applicant relies in seeking approval of its proposed drug product by established name, if any, proprietary name, dosage form, strength, route of administration, name of listed drug's application holder, and listed drug's approved application number.

(iv) If the applicant is seeking approval only for a new indication and not for the indications approved for the listed drug on which the applicant relies, a certification so stating.

(v) Any patent information required under section 505(b)(1) of the act with respect to any patent which claims the drug for which approval is sought or a method of using such drug and to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product.

(vi) Any patent certification or statement required under section 505(b)(2) of the act with respect to any relevant patents that claim the listed drug or that claim any other drugs on which investigations relied on by the applicant for approval of the application were conducted, or that claim a use for the listed or other drug.

(2) The applicant shall submit a review copy that contains the technical sections described in § 314.50(d)(1) and (d)(3), and the technical sections described in § 314.50(d), (d)(4), (d)(5), (d)(6), and (f) when needed to support the modification. Each of the technical sections in the review copy is required to be separately bound with a copy of the information required under § 314.50 (a), (b), and (c) and a copy of the proposed labeling.

(3) The information required by § 314.50 (d)(2), (d)(4) (if an anti-infective drug), (d)(5), (d)(6), and (f) for the listed drug on which the applicant relies shall be satisfied by reference to the listed drug under paragraph (a)(1)(iii) of this section.

(b) An application may not be submitted under this section for a drug product whose only difference from the reference listed drug is that:

(1) The extent to which its active ingredient(s) is absorbed or otherwise made available to the site of action is less than that of the reference listed drug; or

(2) The rate at which its active ingredient(s) is absorbed or otherwise made available to the site of action is

unintentionally less than that of the reference listed drug.

§ 314.55 [Removed]

15. Section 314.55 *Abbreviated application* is removed.

§ 314.56 [Removed]

16. Section 314.56 *Drug products for which abbreviated applications are suitable* is removed.

17. Section 314.60 is amended by redesignating the existing paragraph as paragraph (a) and by revising the first sentence, and by adding a new paragraph (b) to read as follows:

§ 314.60 Amendments to an unapproved application.

(a) Except as provided in paragraph (b) of this section, the applicant may submit an amendment to an application that is filed under § 314.100, but not yet approved. * * *

(b)(1) An unapproved application may not be amended if all of the following conditions apply:

(i) The unapproved application is for a drug for which a previous application has been approved and granted a period of exclusivity in accordance with section 505(c)(3)(D)(ii) of the act that has not expired;

(ii) The applicant seeks to amend the unapproved application to include a published report of an investigation that was conducted or sponsored by the applicant entitled to exclusivity for the drug;

(iii) The applicant has not obtained a right of reference to the investigation described in paragraph (b)(1)(ii) of this section; and

(iv) The report of the investigation described in paragraph (b)(1)(ii) of this section would be essential to the approval of the unapproved application.

(2) The submission of an amendment described in paragraph (b)(1) of this section will cause the unapproved application to be deemed to be withdrawn by the applicant under § 314.65 on the date of receipt by FDA of the amendment. The amendment will be considered a resubmission of the application, which may not be accepted except as provided in accordance with section 505(c)(3)(D)(ii) of the act.

18. Section 314.70 is amended by adding new paragraph (e) to read as follows:

§ 314.70 Supplements and other changes to an approved application.

* * * * *

(e) *Patent information.* The applicant shall comply with the patent information requirements under section 505(c)(2) of the act.

19. Section 314.71 is amended in paragraph (b) by revising the first sentence to read as follows:

§ 314.71 Procedures for submission of a supplement to an approved application.

* * * * *

(b) All procedures and actions that apply to an application under § 314.50 also apply to supplements, except that the information required in the supplement is limited to that needed to support the change. * * *

* * * * *

20. Section 314.80 is amended by removing the word "significant" in the definition of "Adverse drug experience" in paragraph (a), by revising paragraph (b), the first sentence in paragraph (c)(1)(ii), and the last sentence in paragraph (d)(1) to read as follows:

§ 314.80 Postmarketing reporting of adverse drug experiences.

* * * * *

(b) *Review of adverse drug experiences.* Each applicant having an approved application under § 314.50 or, in the case of a 505(b)(2) application, an effective approved application, shall promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers.

(c) * * *

(1) * * *

(ii) The applicant shall review periodically (at least as often as the periodic reporting cycle) the frequency of reports of adverse drug experiences that are both serious and expected and reports of therapeutic failure (lack of effect), regardless of source, and report any significant increase in frequency as soon as possible but in any case within 15 working days of determining that a significant increase in frequency exists. * * *

* * * * *

(d) *Scientific literature.* (1) * * * The 15-day reporting requirements in paragraph (c)(1)(ii) of this section (i.e., a significant increase in frequency of a serious, expected adverse drug experience or of a therapeutic failure) apply only to reports found in scientific and medical journals either as the result of a formal clinical trial, or from epidemiological studies or analyses of experience in a monitored series of patients.

* * * * *

21. Section 314.81 is amended by adding new paragraph (b)(3)(iii) to read as follows:

§ 314.81 Other postmarketing reports.

* * * * *

(b) * * *

(3) * * *

(iii) *Withdrawal of approved drug product from sale.* (*a*) The applicant shall submit on Form FDA 2657 (Drug Product Listing), within 15 working days of the withdrawal from sale of a drug product, the following information:

(*1*) The National Drug Code (NDC) number.

(*2*) The identity of the drug product by established name and by proprietary name.

(*3*) The new drug application or abbreviated application number.

(*4*) The date of withdrawal from sale. It is requested but not required that the reason for withdrawal of the drug product from sale be included with the information.

(*b*) The applicant shall submit each Form FDA-2657 to the Drug Listing Branch (HFD-334), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(*c*) Reporting under paragraph (b)(3)(iii) of this section constitutes compliance with the requirements under § 207.30(a) of this chapter to report "at the discretion of the registrant when the change occurs."

* * * * *

22. Subparts C, D, E, and F are redesignated as Subparts D, E, F, and G, respectively, and new Subpart C, consisting of §§ 314.92 through 314.99, is added to read as follows:

Subpart C—Abbreviated Applications

§ 314.92 Drug products for which abbreviated applications may be submitted.

(a) Abbreviated applications are suitable for the following drug products within the limits set forth under § 314.93:

(1) Drug products that are the same as a listed drug. A "listed drug" is defined in § 314.3. For determining the suitability of an abbreviated new drug application, the term "same as" means identical in active ingredient(s), dosage form, strength, route of administration, and conditions of use, except that conditions of use for which approval cannot be granted because of exclusivity or an existing patent may be omitted. If a listed drug has been voluntarily withdrawn from or not offered for sale by its manufacturer, a person who wishes to submit an abbreviated new

drug application for the drug shall comply with § 314.122.

(2) Drug products that are duplicates of, or that meet the monograph for, an antibiotic drug for which FDA has approved an application.

(3) Drug products that have been declared suitable for an abbreviated new drug application submission by FDA through the petition procedures set forth under § 10.30 of this chapter and § 314.93.

(b) FDA will publish in the list listed drugs for which abbreviated applications may be submitted. The list is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, 202-783-3238.

§ 314.93 Petition to request a change from a listed drug.

(a) The only changes from a listed drug for which the agency will accept a petition under this section are those changes described in paragraph (b) of this section. Petitions to submit abbreviated new drug applications for other changes from a listed drug will not be approved.

(b) A person who wants to submit an abbreviated new drug application for a drug product which is not identical to a listed drug in route of administration, dosage form, and strength, or in which one active ingredient is substituted for one of the active ingredients in a listed combination drug, must first obtain permission from FDA to submit such an abbreviated application.

(c) To obtain permission to submit an abbreviated new drug application for a change described in paragraph (b) of this section, a person must submit and obtain approval of a petition requesting the change. A person seeking permission to request such a change from a reference listed drug shall submit a petition in accordance with §10.20 of this chapter and in the format specified in § 10.30 of this chapter. The petition shall contain the information specified in § 10.30 of this chapter and any additional information required by this section. If any provision of § 10.20 or § 10.30 of this chapter is inconsistent with any provision of this section, the provisions of this section apply.

(d) The petitioner shall identify a listed drug and include a copy of the proposed labeling for the drug product that is the subject of the petition and a copy of the approved labeling for the listed drug. The petitioner may, under limited circumstances, identify more than one listed drug, for example, when the proposed drug product is a combination product that differs from the combination reference listed drug with regard to an active ingredient, and the different active ingredient is an active ingredient of a listed drug. The petitioner shall also include information to show that:

(1) The active ingredients of the proposed drug product are of the same pharmacological or therapeutic class as those of the reference listed drug.

(2) The drug product can be expected to have the same therapeutic effect as the reference listed drug when administered to patients for each condition of use in the reference listed drug's labeling for which the applicant seeks approval.

(3) If the proposed drug product is a combination product with one different active ingredient, including a different ester or salt, from the reference listed drug, that the different active ingredient has previously been approved in a listed drug or is a drug that does not meet the definition of "new drug" in section 201(b) of the act.

(e) No later than 90 days after the date a petition that is permitted under paragraph (a) of this section is submitted, FDA will approve or disapprove the petition.

(1) FDA will approve a petition properly submited under this section unless it finds that:

(i) Investigations must be conducted to show the safety and effectiveness of the drug product or of any of its active ingredients, its route of administration, dosage form, or strength which differs from the reference listed drug; or

(ii) For a petition that seeks to change an active ingredient, the drug product that is the subject of the petition is not a combination drug; or

(iii) For a combination drug product that is the subject of the petition and has an active ingredient different from the reference listed drug:

(A) The drug product may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted under § 314.94; or

(B) The petition does not contain information to show that the different active ingredient of the drug product is of the same pharmacological or therapeutic class as the ingredient of the reference listed drug that is to be changed and that the drug product can be expected to have the same therapeutic effect as the reference listed drug when administered to patients for each condition of use in the listed drug's labeling for which the applicant seeks approval; or

(C) The different active ingredient is not an active ingredient in a listed drug or a drug that meets the requirements of section 201(p) of the act; or

(D) The remaining active ingredients are not identical to those of the listed combination drug; or

(iv) Any of the proposed changes from the listed drug would jeopardize the safe or effective use of the product so as to necessitate significant labeling changes to address the newly introduced safety or effectiveness problem; or

(v) FDA has determined that the reference listed drug has been withdrawn from sale for safety or effectiveness reasons under § 314.161, or the reference listed drug has been voluntarily withdrawn from sale and the agency has not determined whether the withdrawal is for safety or effectiveness reasons.

(2) For purposes of this paragraph, "investigations must be conducted" means that information derived from animal or clinical studies is necessary to show that the drug product is safe or effective. Such information may be contained in published or unpublished reports.

(3) If FDA approves a petition submitted under this section, the agency's response may describe what additional information, if any, will be required to support an abbreviated new drug application for the drug product. FDA may, at any time during the course of its review of an abbreviated new drug application, request additional information required to evaluate the change approved under the petition.

(f) FDA may withdraw approval of a petition if the agency receives any information demonstrating that the petition no longer satisfies the conditions under paragraph (e) of this section.

§ 314.94 Content and format of an abbreviated application.

Abbreviated applications are required to be submitted in the form and contain the information required under this section. Two copies of the application are required, an archival copy and a review copy. FDA will maintain guidelines on the format and content of applications to assist applicants in their preparation.

(a) *Abbreviated new drug applications.* Except as provided in paragraph (b) of this section, the applicant shall submit a complete archival copy of the abbreviated new drug application that includes the following:

(1) *Application form.* The applicant shall submit a completed and signed application form that contains the information described under § 314.50(a)(1), (a)(3), (a)(4), and (a)(5). The applicant shall state whether the

submission is an abbreviated application under this section or a supplement to an abbreviated application under § 314.97.

(2) *Table of contents.* the archival copy of the abbreviated new drug application is required to contain a table of contents that shows the volume number and page number of the contents of the submission.

(3) *Basis for abbreviated new drug application submission.* An abbreviated new drug application must refer to a listed drug. Ordinarily, that listed drug will be the drug product selected by the agency as the reference standard for conducting bioequivalence testing. The application shall contain:

(i) The name of the reference listed drug, including its dosage form and strength. For an abbreviated new drug application based on an approverd petition under §10.30 of this chapter or §314.93, the reference listed drug must be the same as the listed drug approved in the petition.

(ii) A statement as to whether, according to the information published in the list, the reference listed drug is entitled to a period of marketing exclusivity under section 505(j)(4)(D) of the act.

(iii) For an abbreviated new drug application based on an approved petition under § 10.30 of this chapter or § 314.93, a reference to FDA-assigned docket number for the petition and a copy of FDA's correspondence approving the petition.

(4) *Conditions of use.* (i) A statement that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the drug product have been previously approved for the reference listed drug.

(ii) A reference to the applicant's annotated proposed labeling and to the currently approved labeling for the reference listed drug provided under paragraph (a)(8) of this section.

(5) *Active ingredients.* (i) For a single-active-ingredient drug product, information to show that the active ingredient is the same as that of the reference single-active-ingredient listed drug, as follows:

(A) A statement that the active ingredient of the proposed drug product is the same as that of the reference listed drug.

(B) A reference to the applicant's annotated proposed labeling and to the currently approved labeling for the reference listed drug provided under paragraph (a)(8) of this section.

(ii) For a combination drug product, information to show that the active ingredients are the same as those of the reference listed drug except for any different active ingredient that has been the subject of an approved petition, as follows:

(A) A statement that the active ingredients of the proposed drug product are the same as those of the reference listed drug, or if one of the active ingredients differs from one of the active ingredients of the reference listed drug and the abbreviated application is submitted under the approval of a petition under § 314.93 to vary such active ingredient, information to show that the other active ingredients of the drug product are the same as the other active ingredients of the reference listed drug, information to show that the different active ingredient is an active ingredient of another listed drug or of a drug that does not meet the definition of "new drug" in section 201(p) of the act, and such other information about the different active ingredient that FDA may require.

(B) A reference to the applicant's annotated proposed labeling and to the currently approved labeling for the reference listed drug provided under paragraph (a)(8) of this section.

(6) *Route of administration, dosage form, and strength.* (i) Information to show that the route of administration, dosage form, and strength of the drug product are the same as those of the reference listed drug except for any differences that have been the subject of an approved petition, as follows:

(A) A statement that the route of administration, dosage form, and strength of the proposed drug product are the same as those of the reference listed drug.

(B) A reference to the applicant's annotated proposed labeling and to the currently approved labeling for the reference listed drug provided under paragraph (a)(8) of this section.

(ii) If the route of administration, dosage form, or strength of the drug product differs from the reference listed drug and the abbreviated application is submitted under an approved petition under § 314.93, such information about the different route of administration, dosage form, or strength that FDA may require.

(7) *Bioequivalence.* (i) Information that shows that the drug product is bioequivalent to the reference listed drug upon which the applicant relies; or

(ii) If the abbreviated new drug application is submitted under a petition approved under § 314.93, the results of any bioavailability of bioequivalence testing required by the agency, or any other information required by the agency to show that the active ingredients of the proposed drug product are of the same pharmacological or therapeutic class as those in the reference listed drug and that the proposed drug product can be expected to have the same therapeutic effect as the reference listed drug. If the proposed drug product contains a different active ingredient than the reference listed drug, FDA will consider the proposed drug product to have the same therapeutic effect as the reference listed drug if the applicant provides information demonstrating that:

(A) There is an adequate scientific basis for determining that substitution of the specific proposed dose of the different active ingredient for the dose of the member of the same pharmacological or therapeutic class in the reference listed drug will yield a resulting drug product whose safety and effectiveness have not been adversely affected.

(B) The unchanged active ingredients in the proposed drug product are bioequivalent to those in the reference listed drug.

(C) The different active ingredient in the proposed drug product is bioequivalent to an approved dosage form containing that ingredient and approved for the same indication as the proposed drug product or is bioequivalent to a drug product offered for that indication which does not meet the definition of "new drug" under section 201(p) of the act.

(iii) For each in vivo bioequivalence study contained in the abbreviated new drug application, a description of the analytical and statistical methods used in each study and a statement with respect to each study that it either was conducted in compliance with the institutional review board regulations in part 56 of this chapter, or was not subject to the regulations under § 56.104 or § 56.105 of this chapter and that each study was conducted in compliance with the informed consent regulations in part 50 of this chapter.

(8) *Labeling*—(i) *Listed drug labeling.* A copy of the currently approved labeling for the listed drug referred to in the abbreviated new drug application, if the abbreviated new drug application relies on a reference listed drug.

(ii) *Proposed labeling.* Copies of the label and all labeling for the drug product (4 copies of draft labeling or 12 copies of final printed labeling).

(iii) A statement that the applicant's proposed labeling is the same as the labeling of the reference listed drug except for differences annotated and explained under paragraph (a)(8)(iv) of this section.

(iv) A side-by-side comparison of the applicant's proposed labeling with the

approved labeling for the reference listed drug with all differences annotated and explained. Labeling (including the container label and package insert) proposed for the drug product must be the same as the labeling approved for the reference listed drug, except for changes required because of differences approved under a petition filed under § 314.93 or because the drug product and the reference listed drug are produced or distributed by different manufacturers. Such differences between the applicant's proposed labeling and labeling approved for the reference listed drug may include differences in expiration date, formulation, bioavailability, or pharmacokinetics, labeling revisions made to comply with current FDA labeling guidelines or other guidance, or omission of an indication or other aspect of labeling protected by patent or accorded exclusivity under section 505(j)(4)(D) of the act.

(9) *Chemistry, manufacturing, and controls.* (i) The information required under § 314.50(d)(1).

(ii) *Inactive ingredients.* Unless otherwise stated in paragraphs (a)(9)(iii) through (a)(9)(v) of this section, an applicant shall identify and characterize the inactive ingredients in the proposed drug product and provide information demonstrating that such inactive ingredients do not affect the safety of the proposed drug product.

(iii) *Inactive ingredient changes permitted in drug products intended for parenteral use.* Generally, a drug product intended for parenteral use shall contain the same inactive ingredients and in the same concentration as the reference listed drug identified by the applicant under paragraph (a)(3) of this section. However, an applicant may seek approval of a drug product that differs from the reference listed drug in preservative, buffer, or antioxidant provided that the applicant identifies and characterizes the differences and provides information demonstrating that the differences do not affect the safety for the proposed drug product.

(iv) *Inactive ingredient changes permitted in drug products intended for ophthalmic or otic use.* Generally, a drug product intended for ophthalmic or otic use shall contain the same inactive ingredients and in the same concentration as the reference listed drug identified by the applicant under paragraph (a)(3) of this section. However, an applicant may seek approval of a drug product that differs from the reference listed drug in preservative, buffer, substance to adjust tonicity, or thickening agent provided that the applicant identifies and characterizes the differences and provides information demonstrating that the differences do not affect the safety of the proposed drug product, except that, in a product intended for ophthalmic use, an applicant may not change a buffer or substance to adjust tonicity for the purpose of claiming a therapeutic advantage over or difference from the listed drug, e.g., by using a balanced salt solution as a diluent as opposed to an isotonic saline solution, or by making a significant change in the pH or other change that may raise questions of irritability.

(v) *Inactive ingredient changes permitted in drug products intended for topical use.* Generally, a drug product intended for topical use shall contain the same inactive ingredients as the reference listed drug identified by the applicant under paragraph (a)(3) of this section. However, an applicant may seek approval of a drug product that differs from the reference listed drug provided that the applicant identifies and characterizes the differences and provides information demonstrating that the differences do not affect the safety of the proposed drug product.

(10) *Samples.* The information required under § 314.50(e)(1) and (e)(2)(i). Samples need not be submitted until requested by FDA.

(11) *Other.* The information required under § 314.50(g).

(b) *Drug products subject to the Drug Efficacy Study Implementation (DESI) review.* If the abbreviated new drug application is for a duplicate of a drug product that is subject to FDA's DESI review (a review of drug products approved as safe between 1938 and 1962) or other DESI-like review and the drug product evaluated in the review is a listed drug, the applicant shall comply with the provisions of paragraph (a) of this section.

(c) *Abbreviated antibiotic application.* For applications submitted under section 507 of the act, the applicant shall submit a complete archival copy of the abbreviated application that contains the information described under § 314.50 (a)(1), (a)(3), (a)(4), and (a)(5), (b), (d)(1) and (d)(3), (e), and (g). The applicant shall state whether the submission is an abbreviated application under this section or a supplement to an abbreviated application under § 314.97.

(d) *Format of an abbreviated application.* (1) The applicant shall submit a complete archival copy of the abbreviated application as required under paragraphs (a) and (c) of this section. FDA will maintain the archival copy during the review of the application to permit individual reviewers to refer to information that is not contained in their particular technical sections of the application, to give other agency personnel access to the application for official business, and to maintain in one place a complete copy of the application. An applicant may submit all or portions of the archival copy of the abbreviated application in any form (e.g., microfiche, optical disc, and magnetic tape) that the applicant and FDA agree is acceptable.

(2) For abbreviated new drug applications, the applicant shall submit a review copy of the abbreviated application that contains two separate sections. One section shall contain the information described under paragraphs (a)(2) through (a)(6), (a)(8), and (a)(9) of this section 505(j)(2)(A)(vii) of the act and one copy of the analytical methods and descriptive information needed by FDA's laboratories to perform tests on samples of the proposed drug product and to validate the applicant's analytical methods. The other section shall contain the information described under paragraphs (a)(3), (a)(7), and (a)(8) of this section. Each of the sections in the review copy is required to contain a copy of the application form described under § 314.50(a).

(3) For abbreviated antibiotic applications, the applicant shall submit a review copy that contains the technical sections described in § 314.50 (d)(1) and (d)(3). Each of the technical sections in the review copy is required to be separate with a copy of the application form required under § 314.50(a).

(4) The applicant may obtain from FDA sufficient folders to bind the archival and the review copies of the abbreviated application.

§ 314.96 Amendments to an unapproved abbreviated application.

(a) *Abbreviated new drug application.* (1) An applicant may amend an abbreviated new drug application that is submitted under § 314.94, but not yet approved, to revise existing information or provide additional information.

(2) Submission of an amendment containing significant data or information constitutes an agreement between FDA and the applicant to extend the review period only for the time necessary to review the significant data or information and for no more than 180 days.

(3) Submission of an amendment containing significant data or information to resolve deficiencies in the application as set forth in a not approvable letter issued under § 314.120 constitutes an agreement between FDA and the applicant under section

505(j)(4)(A) of the act to extend the date by which the agency is required to reach a decision on the abbreviated new drug application only for the time necessary to review the significant data or information and for no more than 180 days.

(b) *Abbreviated antibiotic application.* The applicant shall comply with the provisions of § 314.60.

§ 314.97 Supplements and other changes to an approved abbreviated application.

The applicant shall comply with the requirements of §§ 314.70 and 314.71 regarding the submission of supplemental applications and other changes to an approved abbreviated application.

§ 314.98 Postmarketing reports.

(a) Except as provided in paragraph (b) of this section, each applicant having an approved abbreviated antibiotic application under § 314.94 or approved abbreviated new drug application under § 314.94 that is effective shall comply with the requirements of § 314.80 regarding the reporting and recordkeeping of adverse drug experiences.

(b) Each applicant shall submit one copy of each report required under § 314.80 to the Division of Epidemiology and Surveillance (HFD–730), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(c) Each applicant shall make the reports required under § 314.81 and sections 505(k) and 507(g) of the act for each of its approved abbreviated applications.

§ 314.99 Other responsibilities of an applicant of an abbreviated application.

(a) An applicant shall comply with the requirements of § 314.65 regarding withdrawal by the applicant of an unapproved abbreviated application and § 314.72 regarding a change in ownership of an abbreviated application.

(b) An applicant may ask FDA to waive under this section any requirement that applies to the applicant under §§ 314.92 through 314.99. The applicant shall comply with the requirements for a waiver under § 314.90.

23. The heading for subpart D is revised to read as follows:

Subpart D—FDA Action on Applications and Abbreviated Applications

24. Section 314.100 is revised to read as follows:

§ 314.100 Timeframes for reviewing applications and abbreviated applications.

(a) Within 180 days of receipt of an application for a new drug under section 505(b) of the act, or of an abbreviated application for a new drug under section 505(j) of the act, or of an application or abbreviated application for an antibiotic drug under section 507 of the act, FDA will review it and send the applicant either an approval letter under § 314.105, or an approvable letter under § 314.110, or a not approvable letter under § 314.120. This 180-day period is called the "review clock."

(b) During the review period, an applicant may withdraw an application under § 314.65 or an abbreviated application under § 314.99 and later resubmit it. FDA will treat the resubmission as a new application or abbreviated application.

(c) The review clock may be extended by mutual agreement between FDA and an applicant or as provided in §§ 314.60 and 314.96, as the result of a major amendment.

25. Section 314.101 is revised to read as follows:

§ 314.101 Filing an application and an abbreviated antibiotic application and receiving an abbreviated new drug application.

(a)(1) Within 60 days after FDA receives an application or abbreviated antibiotic application, the agency will determine whether the application or abbreviated antibiotic application may be filed. The filing of an application or abbreviated antibiotic application means that FDA has made a threshold determination that the application or abbreviated antibiotic application is sufficiently complete to permit a substantive review.

(2) If FDA finds that none of the reasons in paragraphs (d) and (e) of this section for refusing to file the application or abbreviated antibiotic apply, the agency will file the application or abbreviated antibiotic application and notify the applicant in writing. The date of filing will be the date 60 days after the date FDA received the application or abbreviated antibiotic application. The date of filing begins the 180-day period described in section 505(c) of the act. This 180-day period is called the "filing clock."

(3) If FDA refuses to file the application or abbreviated antibiotic application, the agency will notify the applicant in writing and state the reason under paragraph (d) or (e) of this section for the refusal. If FDA refuses to file the application or abbreviated antibiotic application under paragraph (d) of this section, the applicant may request in writing within 30 days of the date of the agency's notification an informal conference with the agency about whether the agency should file the application or abbreviated antibiotic application. If, following the informal conference, the applicant requests that FDA file the application or abbreviated antibiotic application (with or without amendments to correct the deficiencies), the agency will file the application or abbreviated antibiotic application over protest under paragraph (a)(2) of this section, notify the applicant in writing, and review it as filed. If the application or abbreviated antibiotic application is filed over protest, the date of filing will be the date 60 days after the date the applicant requested the informal conference. The applicant need not resubmit a copy of an application or abbreviated antibiotic application that is filed over protest. If FDA refuses to file the application or abbreviated antibiotic application under paragraph (e) of this section, the applicant may amend the application or abbreviated antibiotic application and resubmit it, and the agency will make a determination under this section whether it may be filed.

(b)(1) An abbreviated new drug application will be reviewed after it is submitted to determine whether the abbreviated application may be received. Receipt of an abbreviated new drug application means that FDA has made a threshold determination that the abbreviated application is sufficiently complete to permit a substantive review.

(2) If FDA finds that none of the reasons in paragraphs (d) and (e) of this section for considering the abbreviated new drug application not to have been received applies, the agency will receive the abbreviated new drug application and notify the applicant in writing.

(3) If FDA considers the abbreviated new drug application not to have been received under paragraph (d) or (e) of this section, FDA will notify the applicant, ordinarily by telephone. The applicant may then:

(i) Withdraw the abbreviated new drug application under § 314.99; or

(ii) Amend the abbreviated new drug application to correct the deficiencies; or

(iii) Take no action, in which case FDA will refuse to receive the abbreviated new drug application.

(c) [Reserved]

(d) FDA may refuse to file an application or abbreviated antibiotic application or may not consider an abbreviated new drug application to be received if any of the following applies:

(1) The application or abbreviated application does not contain a completed application form.

(2) The application or abbreviated application is not submitted in the form required under § 314.50 or § 314.94.

(3) The application or abbreviated application is incomplete becasue it does not on its face contain information required under section 505(b), section 505(j), or section 507 of the act and § 314.50 or § 314.94.

(4) The applicant fails to submit a complete environmental assessment, which address each of the items specified in the applicable format under § 25.31 of this chapter or fails to provide sufficient information to establish that the requested action is subject to categorical exclusion under § 25.24 of this chapter.

(5) The application or abbreviated application does not contain an accurate and complete English translation of each part of the application that is not in English.

(6) The application does not contain a statement for each nonclinical laboratory study that it was conducted in compliance with the requirements set forth in part 58 of this chapter, or, for each study not conducted in compliance with part 58 of this chapter, a brief statement of the reason for the noncompliance.

(7) The application does not contain a statement for each clinical study that it was conducted in compliance with the institutional review board regulations in part 56 of this chapter, or was not subject to those regulations, and that it was conducted in compliance with the informed consent regulations in part 50 of this chapter, or, if the study was subject to but was not conducted in compliance with those regulations, the application does not contain a brief statement of the reason for the noncompliance.

(8) The drug product that is the subject of the submission is already covered by an approved application or abbreviated application and the applicant of the submission:

(i) Has an approved application or abbreviated application for the same drug product; or

(ii) Is merely a distributor and/or repackager of the already approved drug product.

(9) The application is submitted as a 505(b)(2) application for a drug that is a duplicate of a listed drug and is eligible for approval under section 505(j) of the act.

(e) The agency will refuse to file an application or an abbreviated antibiotic application or will consider an abbreviated new drug application not to have been received if the drug product is subject to licensing by FDA under the Public Health Service Act (42 U.S.C. 201 *et seq.*) and subchapter F of this chapter.

(f)(1) Within 180 days after the date of filing, plus the period of time the review period was extended (if any), FDA will either:

(i) Approve the application or abbreviated antibiotic application; or

(ii) Issue a notice of opportunity for hearing if the applicant asked FDA to provide it an opportunity for a hearing on an application or abbreviated antibiotic application in response to an approvable letter or a not approvable letter.

(2) Within 180 days after the date of receipt, plus the period of time the review clock was extended (if any), FDA will either approve or disapprove the abbreviated new drug application. If FDA disapproves the abbreviated new drug application, FDA will issue a notice of opportunity for hearing if the applicant asked FDA to provide it an opportunity for a hearing on an abbreviated new drug application in response to a not approvable letter.

(3) This paragraph does not apply to applications or abbreviated applications that have been withdrawn from FDA review by the applicant.

26. Section 314.102 is revised to read as follows:

§ 314.102 Communications between FDA and applicants.

(a) *General principles.* During the course of reviewing an application or an abbreviated application, FDA shall communicate with applicants about scientific, medical, and procedural issues that arise during the review process. Such communication may take the form of telephone conversations, letters, or meetings, whichever is most appropriate to discuss the particular issue at hand. Communications shall be appropriately documented in the application in accordance with § 10.65 of this chapter. Further details on the procedures for communication between FDA and applicants are contained in a staff manual guide that is publicly available.

(b) *Notification of easily correctable deficiencies.* FDA reviewers shall make every reasonable effort to communicate promptly to applicants easily correctable deficiencies found in an application or an abbreviated application when those deficiencies are discovered, particularly deficiencies concerning chemistry, manufacturing, and controls issues. The agency will also inform applicants promptly of its need for more data or information or for technical changes in the application or the abbreviated application needed to facilitate the agency review. This early communication is intended to permit applicants to correct such readily identified deficiencies relatively early in the review process and to submit an amendment before the review period has elapsed. Such early communication would not ordinarily apply to major scientific issues, which require consideration of the entire pending application or abbreviated application by agency managers as well as reviewing staff. Instead, major scientific issues will ordinarily be addressed in an action letter.

(c) *Ninety-day conference.* Approximately 90 days after the agency receives the application, FDA will provide applicants with an opportunity to meet with agency reviewing officials. The purpose of the meeting will be to inform applicants of the general progress and status of their applications, and to advise applicants of deficiencies that have been identified by that time and that have not already been communicated. This meeting will be available on applications for all new chemical entities and major new indications of marketed drugs. Such meetings will be held at the applicant's option, and may be held by telephone if mutually agreed upon. Such meetings would not ordinarily be held on abbreviated applications because they are not submitted for new chemical entities or new indications.

(d) *End of review conference.* At the conclusion of FDA's review of an application or an abbreviated application as designated by the issuance of an approvable or not approvable letter, FDA will provide applicants with an opportunity to meet with agency reviewing officials. The purpose of the meeting will be to discuss what further steps need to be taken by the applicant before the application or abbreviated application can be approved. This meeting will be available on all applications or abbreviated applications, with priority given to applications for new chemical entities and major new indications for marketed drugs and for the first duplicates for such drugs. Requests for such meetings shall be directed to the director of the division responsible for reviewing the application or abbreviated application.

(e) *Other meetings.* Other meetings between FDA and applicants may be held, with advance notice, to discuss scientific, medical, and other issues that arise during the review process. Requests for meetings shall be directed to the director of the division

responsible for reviewing the application or abbreviated application. FDA will make every attempt to grant requests for meetings that involve important issues and that can be scheduled at mutually convenient times. However, "drop-in" visits (i.e., an unannounced and unscheduled visit by a company representative) are discouraged except for urgent matters, such as to discuss an important new safety issue.

27. Section 314.103 is amended by revising paragraph (a), the first sentence in paragraph (b), and the fourth sentence in paragraph (c)(2) to read as follows:

§ 314.103 Dispute resolution.

(a) *General.* FDA is committed to resolving differences between applicants and FDA reviewing divisions with respect to technical requirements for applications or abbreviated applications as quickly and amicably as possible through the cooperative exchange of information and views.

(b) *Administrative and procedural issues.* When administrative or procedural disputes arise, the applicant should first attempt to resolve the matter with the division responsible for reviewing the application or abbreviated application, beginning with the consumer safety officer assigned to the application or abbreviated application. * * *

(c) * * *

(2) * * * Requests for such meetings shall be directed to the director of the division responsible for reviewing the application or abbreviated application. * * *

* * * * *

28. Section 314.104 is revised to read as follows:

§ 314.104 Drugs with potential for abuse.

The Food and Drug Administration will inform the Drug Enforcement Administration under section 201(f) of the Controlled Substances Act (21 U.S.C. 801) when an application or abbreviated application is submitted for a drug that appears to have an abuse potential.

29. Section 314.105 is revised to read as follows:

§ 314.105 Approval of an application and an abbreviated application.

(a) The Food and Drug Administration will approve an application or an abbreviated antibiotic application and sent the applicant an approval letter if none of the reasons in § 314.125 for refusing to approve the application or abbreviated antibiotic application applies. An approval becomes effective on the date of the issuance of the approval letter, except with regard to an approval under section 505(b)(2) of the act with a delayed effective date. An approval with a delayed effective date is tentative and does not become final until the effective date. When FDA sends an applicant an approval letter for an antibiotic, it will promulgate a regulation under § 314.300 providing for certification of the drug, if necessary. A new drug product or antibiotic approved under this paragraph may not be marketed until an approval is effective. Marketing of an antibiotic need not await the promulgation of a regulation under § 314.300.

(b) FDA will approve an application or abbreviated antibiotic application and issue the applicant an approval letter (rather than an approvable letter under § 314.110) on the basis of draft labeling if the only deficiencies in the application or abbreviated antibiotic application concern editorial or similar minor deficiencies in the draft labeling. Such approval will be conditioned upon the applicant incorporating the specified labeling changes exactly as directed, and upon the applicant submitting to FDA a copy of the final printed labeling prior to marketing.

(c) FDA will approve an application after it determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling, and an abbreviated application after it determines that the drug meets the statutory standards for manufacturing and controls, labeling, and, where applicable, bioequivalence. While the statutory standards apply to all drugs, the many kinds of drugs that are subject to the statutory standards and the wide range of uses for those drugs demand flexibility in applying the standards. Thus FDA is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards. FDA makes its views on drug products and classes of drugs available through guidelines, recommendations, and other statements of policy.

(d) FDA will approve an abbreviated new drug application and send the applicant an approval letter if none of the reasons in § 314.127 for refusing to approve the abbreviated new drug application applies. The approval becomes effective on the date of the issuance of the agency's approval letter unless the approval letter provides for a delayed effective date. An approval with a delayed effective date is tentative and does not become final until the effective date. A new drug product approved under this paragraph may not be introduced or delivered for introduction into interstate commerce until approval of the abbreviated new drug application is effective. Ordinarily, the effective date of approval will be stated in the approval letter.

30. Section 314.110 is revised to read as follows:

§ 314.110 Approvable letter to the applicant.

(a) In selected circumstances, it is useful at the end of the review period for the Food and Drug Administration to indicate to the applicant that the application or abbreviated application is basically approvable providing certain issues are resolved. An approvable letter may be issued in such circumstances. FDA will send the applicant an approvable letter if the application or abbreviated application substantially meets the requirements of this part and the agency believes that it can approve the application or abbreviated application if specific additional information or material is submitted or specific conditions (for example, certain changes in labeling) are agreed to by the applicant. The approvable letter will describe the information or material FDA requires or the conditions the applicant is asked to meet. As a practical matter, the approvable letter will serve in most instances as a mechanism for resolving outstanding issues on drugs that are about to be approved and marketed. For an application or an abbreviated antibiotic application, the applicant shall, within 10 days after the date of the approvable letter:

(1) Amend the application or abbreviated antibiotic application or notify FDA of an intent to file an amendment. The filing of an amendment or notice of intent to file an amendment constitutes an agreement by the applicant to extend the review period for 45 days after the date FDA receives the amendment. The extension is to permit the agency to review the amendment;

(2) Withdraw the application or abbreviated antibiotic application. FDA will consider the applicant's failure to respond within 10 days to an approvable letter to be a request by the applicant to withdraw the application under § 314.65 or the abbreviated antibiotic application under § 314.99. A decision to withdraw an application or abbreviated antibiotic application is without prejudice to a refiling;

(3) For a new drug application or abbreviated antibiotic application, ask the agency to provide the applicant an opportunity for a hearing on the

question of whether there are grounds for denying approval of the application under section 505(d) of the act. The applicant shall submit the request to the Division of Regulatory Affairs (HFD-360), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Within 60 days of the date of the approvable letter, or within a different time period to which FDA and the applicant agree, the agency will either approve the application or abbreviated antibiotic application under § 314.105 or refuse to approve the application or abbreviated antibiotic application under § 314.125 and give the applicant written notice of an opportunity for a hearing under § 314.200 and section 505(c)(2) of the act on the question of whether there are grounds for denying approval of the application under section 505(d) of the act;

(4) For an antibiotic, file a petition or notify FDA of an intent to file a petition proposing the issuance, amendment, or repeal of a regulation under § 314.300 and section 507(f) of the act; or

(5) Notify FDA that the applicant agrees to an extension of the review period under section 505(c) of the act, so that the applicant can determine whether to respond further under paragraph (a)(1), (a)(2), (a)(3), or (a)(4) of this section. The applicant's notice is required to state the length of the extension. FDA will honor any reasonable request for such an extension. FDA will consider the applicant's failure to respond further within the extended review period to be a request to withdraw the application under § 314.65 or the abbreviated antibiotic application under § 314.99. A decision to withdraw an application or abbreviated antibiotic application is without prejudice to a refiling.

(b) FDA will send the applicant of an abbreviated new drug application an approvable letter only if the application substantially meets the requirements of this part and the agency believes that it can approve the abbreviated application if minor deficiencies (e.g., labeling deficiencies) are corrected. The approvable letter will describe the deficiencies and state a time period within which the applicant must respond. Unless the applicant corrects the deficiencies by amendment within the specified time period, FDA will refuse to approve the abbreviated application under § 314.127. Within 10 days after the date of the approvable letter, the applicant may also ask the agency to provide the applicant an opportunity for a hearing on the question of whether there are grounds for denying approval of the abbreviated new drug application. Applicants who request a hearing shall submit the request to the Division of Regulatory Affairs (HFD-360), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

31. Section 314.120 is revised to read as follows:

§ 314.120 Not approvable letter to the applicant.

(a) The Food and Drug Administration will send the applicant a not approvable letter if the agency believes that the application or abbreviated antibiotic application may not be approved for one of the reasons given in § 314.125 or the abbreviated new drug application may not be approved for one of the reasons given in § 314.127. The not approvable letter will describe the deficiencies in the application or abbreviated application. Except as provided in paragraph (b) of this section, within 10 days after the date of the not approvable letter, the applicant shall:

(1) Amend the application or abbreviated application or notify FDA of an intent to file an amendment. The filing of an amendment or a notice of intent to file an amendment constitutes an agreement by the applicant to extend the review period under § 314.60 or § 314.96;

(2) Withdraw the application or abbreviated application. Except as provided in paragraph (b) of this section, FDA will consider the applicant's failure to respond within 10 days to a not approvable letter to be a request by the applicant to withdraw the application under § 314.65 or abbreviated application under § 314.99. A decision to withdraw the application or abbreviated application is without prejudice to refiling;

(3) For a new drug application or an abbreviated application, ask the agency to provide the applicant an opportunity for a hearing on the question of whether there are grounds for denying approval of the application under section 505(d) or (j)(3) of the act. The applicant shall submit the request to the Division of Regulatory Affairs (HFD-360), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Within 60 days of the date of the not approvable letter, or within a different time period to which FDA and the applicant agree, the agency will either approve the application or abbreviated application under § 314.105 or refuse to approve the application or abbreviated antibiotic application under § 314.125 or abbreviated new drug application under § 314.127 and give the applicant written notice of an opportunity for a hearing under § 314.200 and section 505(c)(1)(B) or (j)(4)(C) of the act on the question of whether there are grounds for denying approval of the application under section 505(d) or (j)(3) of the act;

(4) For an antibiotic application, file a petition or notify FDA of an intent to file a petition proposing the issuance, amendment, or repeal of a regulation under § 314.300 and section 507(f) of the act; or

(5) Notify FDA that the applicant agrees to an extension of the review period under section 505(c)(1) or (j)(4)(A) of the act, so that the applicant can determine whether to respond further under paragraph (a)(1), (a)(2), (a)(3), or (a)(4) of this section. The applicant's notice is required to state the length of the extension. FDA will honor any reasonable request for such an extension. FDA will consider the applicant's failure to respond further within the extended review period to be a request to withdraw the application under § 314.65 or abbreviated application under § 314.99. A decision to withdraw an application or abbreviated application is without prejudice to a refiling.

(b) With the exception of a request for an opportunity for a hearing under paragraph (a)(3) of this section, the 10-day time period in this section for responding to a not approvable letter does not apply to abbreviated new drug applications. FDA may consider the applicant's failure to respond within 180 days to a not approvable letter to be a request by the applicant to withdraw the abbreviated new drug application under § 314.99.

32. New § 314.122 is added to subpart D to read as follows:

§ 314.122 Submitting an abbreviated application for, or a 505(j)(2)(C) petition that relies on, a listed drug that is no longer marketed.

(a) An abbreviated new drug application that refers to, or a petition under section 505(j)(2)(C) of the act and § 314.93 that relies on, a listed drug that has been voluntarily withdrawn from sale in the United States must be accompanied by a petition seeking a determination whether the listed drug was withdrawn for safety or effectiveness reasons. The petition must be submitted under §§ 10.25(a) and 10.30 of this chapter and must contain all evidence available to the petitioner concerning the reasons for the withdrawal from sale.

(b) When a petition described in paragraph (a) of this section is submitted, the agency will consider the evidence in the petition and any other evidence before the agency, and determine whether the listed drug is withdrawn from sale for safety or effectiveness reasons, in accordance with procedures in § 314.161.

(c) An abbreviated new drug application described in paragraph (a) of this section will be disapproved, under § 314.127(a)(11), and a 505(j)(2)(C) petition described in paragraph (a) of this section will be disapproved, under § 314.93(e)(1)(iv), unless the agency determines that the withdrawal of the listed drug was not for safety or effectiveness reasons.

(d) Certain drug products approved for safety and effectiveness that were no longer marketed on September 24, 1984, are not included in the list. Any person who wishes to obtain marketing approval for such a drug product under an abbreviated new drug application must petition FDA for a determination whether the drug product was withdrawn from the market for safety or effectiveness reasons and request that the list be amended to include the drug product. A person seeking such a determination shall use the petition procedures established in § 10.30 of this chapter. The petitioner shall include in the petition information to show that the drug product was approved for safety and effectiveness and all evidence available to the petitioner concerning the reason that marketing of the drug product ceased.

33. Section 314.125 is amended by revising the section heading, the introductory text of paragraph (a), the introductory text of paragraph (b), paragraphs (b)(7), (b)(9), (b)(10), (b)(12), (b)(14), (b)(15), (b)(16), and (b)(17), and by adding new paragraph (b)(18) to read as follows:

§ 314.125 Refusal to approve an application or abbreviated antibiotic application.

(a) The Food and Drug Administration will refuse to approve the application or abbreviated antibiotic application and for a new drug give the applicant written notice of an opportunity for a hearing under § 314.200 on the question of whether there are grounds for denying approval of the application under section 505(d) of the act, or for an antibiotic publish a proposed regulation based on an acceptable petition under § 314.300, if:

* * * * *

(b) FDA may refuse to approve an application or abbreviated antibiotic application for any of the following reasons:

* * * * *

(7) The application or abbreviated antibiotic application contains an untrue statement of a material fact.

* * * * *

(9) The application or abbreviated antibiotic application does not contain bioavailability or bioequivalence data required under part 320 of this chapter.

(10) A reason given in a letter refusing to file the application or abbreviated antibiotic application under § 314.101(d), if the deficiency is not corrected.

* * * * *

(12) The applicant does not permit a properly authorized officer or employee of the Department of Health and Human Services an adequate opportunity to inspect the facilities, controls, and any records relevant to the application or abbreviated antibiotic application.

* * * * *

(14) The application or abbreviated antibiotic application does not contain an explanation of the omission of a report of any investigation of the drug product sponsored by the applicant, or an explanation of the omission of other information about the drug pertinent to an evaluation of the application or abbreviated antibiotic application that is received or otherwise obtained by the applicant from any source.

(15) A nonclinical laboratory study that is described in the application or abbreviated antibiotic application and that is essential to show that the drug is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling was not conducted in compliance with the good laboratory practice regulations in part 58 of this chapter and no reason for the noncompliance is provided or, if it is, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study.

(16) Any clinical investigation involving human subjects described in the application or abbreviated antibiotic application, subject to the institutional review board regulations in part 58 of this chapter or informed consent regulations in part 50 of this chapter, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected.

(17) The applicant or contract research organization that conducted a bioavailability or bioequivalence study contained in the application or abbreviated antibiotic application refuses to permit an inspection of facilities or records relevant to the study by a properly authorized officer or employee of the Department of Health and Human Services or refuses to submit reserve samples of the drug products used in the study when requested by FDA.

(18) For a new drug, the application failed to contain the patent information required by section 505(b)(1) of the act.

* * * * *

34. New § 314.127 is added to subpart D to read as follows:

§ 314.127 Refusal to approve an abbreviated new drug application.

(a) FDA will refuse to approve an abbreviated application for a new drug under section 505(j) of the act for any of the following reasons:

(1) The methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug product are inadequate to ensure and preserve its identity, strength, quality, and purity.

(2) Information submitted with the abbreviated new drug application is insufficient to show that each of the proposed conditions of use has been previously approved for the listed drug referred to in the application.

(3)(i) If the reference listed drug has only one active ingredient, information submitted with the abbreviated new drug application is insufficient to show that the active ingredient is the same as that of the reference listed drug;

(ii) If the reference listed drug has more than one active ingredient, information submitted with the abbreviated new drug application is insufficient to show that the active ingredients are the same as the active ingredients of the reference listed drug; or

(iii) If the reference listed drug has more than one active ingredient and if the abbreviated new drug application is for a drug product that has an active ingredient different from the reference listed drug:

(A) Information submitted with the abbreviated new drug application is insufficient to show:

(*1*) That the other active ingredient are the same as the active ingredients of the reference listed drug; or

(*2*) That the different active ingredient is an active ingredient of a listed drug or a drug that does not meet the requirements of section 201(p) of the act; or

(b) No petition to submit an abbreviated application for the drug product with the different active ingredient was approved under § 314.93.

(4)(i) If the abbreviated new drug application is for a drug product whose

route of administration, dosage form, or strength purports to be the same as that of the listed drug referred to in the abbreviated new drug application, information submitted in the abbreviated new drug application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the reference listed drug; or

(ii) If the abbreviated new drug application is for a drug product whose route of administration, dosage form, or strength is different from that of the listed drug referred to in the application, no petition to submit an abbreviated new drug application for the drug product with the different route of administration, dosage form, or strength was approved under § 314.93.

(5) If the abbreviated new drug application was submitted under the approval of a petition under § 314.93, the abbreviated new drug application did not contain the information required by FDA with respect to the active ingredient, route of administration, dosage form, or strength that is not the same as that of the reference listed drug.

(6)(i) Information submitted in the abbreviated new drug application is insufficient to show that the drug product is bioequivalent to the listed drug referred to in the abbreviated new drug application; or

(ii) If the abbreviated new drug application was submitted under a petition approved under § 314.93, information submitted in the abbreviated new drug application is insufficient to show that the active ingredients of the drug product are of the same pharmacological or therapeutic class as those of the reference listed drug and that the drug product can be expected to have the same therapeutic effect as the reference listed drug when administered to patients for each condition of use approved for the reference listed drug.

(7) Information submitted in the abbreviated new drug application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the abbreviated new drug application except for changes required because of differences approved in a petition under § 314.93 or because the drug product and the reference listed drug are produced or distributed by different manufacturers or because aspects of the listed drug's labeling are protected by patent, or by exclusivity, and such differences do not render the proposed drug product less safe or effective than the listed drug for all remaining, nonprotected conditions of use.

(8)(i) Information submitted in the abbreviated new drug application of any other information available to FDA shows that:

(A) The inactive ingredients of the drug product are unsafe for use, as described in paragraph (a)(8)(ii) of this section, under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug product; or

(B) The composition of the drug product is unsafe, as described in paragraph (a)(8)(ii) of this section, under the conditions prescribed, recommended, or suggested in the proposed labeling because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included.

(ii)(A) FDA will consider the inactive ingredients or composition of a drug product unsafe and refuse to approve an abbreviated new drug application under paragraph (a)(8)(i) of this section if, on the basis of information available to the agency, there is a reasonable basis to conclude that one or more of the inactive ingredients of the proposed drug or its composition raises serious questions of safety. From its experience with reviewing inactive ingredients, and from other information available to it, FDA may identify changes in inactive ingredients or composition that may adversely affect a drug product's safety. The inactive ingredients or composition of a proposed drug product will be considered to raise serious questions of safety if the product incorporates one or more of these changes. Examples of the changes that may raise serious questions of safety include, but are not limited to, the following:

(*1*) A change in an inactive ingredient so that the product does not comply with an official compendium.

(*2*) A change in composition to include an inactive ingredient that has not been previously approved in a drug product for human use by the same route of administration.

(*3*) A change in the composition of a parenteral drug product to include an inactive ingredient that has not been previously approved in a parenteral drug product.

(*4*) A change in composition of a drug product for ophthalmic use to include an inactive ingredient that has not been previously approved in a drug for ophthalmic use.

(*5*) The use of a delivery or a modified release mechanism never before approved for the drug.

(*6*) A change in composition to include a significantly greater content of one or more inactive ingredients than previously used in the drug product.

(*7*) If the drug product is intended for topical administration, a change in the properties of the vehicle or base that might increase absorption of certain potentially toxic active ingredients thereby affecting the safety of the drug product, or a change in the lipophilic properties of a vehicle or base, e.g., a change from an oleaginous to a water soluble vehicle or base.

(B) FDA will consider an inactive ingredient in, or the composition of, a drug product intended for parenteral use to be unsafe and will refuse to approve the abbreviated new drug application unless it contains the same inactive ingredients, other than preservatives, buffers, and antioxidants, in the same concentration as the listed drug, and, if it differs from the listed drug in a preservative, buffer, or antioxidant, the application contains sufficient information to demonstrate that the difference does not affect the safety of the drug product.

(C) FDA will consider an inactive ingredient in, or the composition of, a drug product intended for ophthalmic or otic use unsafe and will refuse to approve the abbreviated new drug application unless it contains the same inactive ingredients, other than preservatives, buffers, substances to adjust tonicity, or thickening agents, in the same concentration as the listed drug, and if it differs from the listed drug in a preservative, buffer, substance to adjust tonicity, or thickening agent, the application contains sufficient information to demonstrate that the difference does not affect the safety of the drug product and the labeling does not claim any therapeutic advantage over or difference from the listed drug.

(9) Approval of the listed drug referred to in the abbreviated new drug application has been withdrawn or suspended for grounds described in § 314.150(a) or FDA has published a notice of opportunity for hearing to withdraw approval of the reference listed drug under § 314.150(a).

(10) Approval of the listed drug referred to in the abbreviated new drug application has been withdrawn under § 314.151 or FDA has proposed to withdraw approval of the reference listed drug under § 314.151(a).

(11) FDA has determined that the reference listed drug has been withdrawn from sale for safety or effectiveness reasons under § 314.161, or the reference listed drug has been voluntarily withdrawn from sale and the agency has not determined whether the withdrawal is for safety or effectiveness reasons, or approval of the reference listed drug has been suspended under

§ 314.153, or the agency has issued an initial decision proposing to suspend the reference listed drug under § 314.153(a)(1).

(12) The abbreviated new drug application does not meet any other requirement under section 505(j)(2)(A) of the act.

(13) The abbreviated new drug application contains an untrue statement of material fact.

(b) FDA may refuse to approve an abbreviated application for a new drug if the applicant or contract research organization that conducted a bioavailability or bioequivalence study contained in the abbreviated new drug application refuses to permit an inspection of facilities or records relevant to the study by a properly authorized officer or employee of the Department of Health and Human Services or refuses to submit reserve samples of the drug products used in the study when requested by FDA.

35. Section 314.150 is revised to read as follows:

§ 314.150 Withdrawal of approval of an application or abbreviated application.

(a) The Food and Drug Administration will notify the applicant, and, if appropriate, all other persons who manufacture or distribute identical, related, or similar drug products as defined in §§ 310.6 and 314.151(a) of this chapter and for a new drug afford an opportunity for a hearing on a proposal to withdraw approval of the application or abbreviated new drug application under section 505(e) of the act and under the procedure in § 314.200, or, for an antibiotic, rescind a certification or release, or amend or repeal a regulation providing for certification under section 507 of the act and under the procedure in § 314.300, if any of the following apply:

(1) The Secretary of Health and Human Services has suspended the approval of the application or abbreviated application for a new drug on a finding that there is an imminent hazard to the public health. FDA will promptly afford the applicant an expedited hearing following summary suspension on a finding of imminent hazard to health.

(2) FDA finds:

(i) That clinical or other experience, tests, or other scientific data show that the drug is unsafe for use under the conditions of use upon the basis of which the application or abbreviated application was approved; or

(ii) That new evidence of clinical experience, not contained in the application or not available to FDA until after the application or abbreviated application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when the application or abbreviated application was approved, evaluated together with the evidence available when the application or abbreviated application was approved, reveal that the drug is not shown to be safe for use under the conditions of use upon the basis of which the application or abbreviated application was approved; or

(iii) Upon the basis of new information before FDA with respect to the drug, evaluated together with the evidence available when the application or abbreviated application was approved, that there is a lack of substantial evidence from adequate and well-controlled investigations as defined in § 314.126, that the drug will have the effect it is purported or represented to have under the conditions of use prescribed, recommended, or suggested in its labeling; or

(iv) That the application or abbreviated application contains any untrue statement of a material fact; or

(v) That the patent information prescribed by section 505(c) of the act was not submitted within 30 days after the receipt of written notice from FDA specifying the failure to submit such information; or

(b) FDA may notify the applicant, and, if appropriate, all other persons who manufacture or distribute identical, related, or similar drug products as defined in § 310.6, and for a new drug afford an opportunity for a hearing on a proposal to withdraw approval of the application or abbreviated new drug application under section 505(e) of the act and under the procedure in § 314.200, or, for an antibiotic, rescind a certification or release, or amend or repeal a regulation providing for certification under section 507 of the act and the procedure in § 314.300, if the agency finds:

(1) That the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain required records or to make required reports under section 505(k) or 507(g) of the act and § 314.80, § 314.81, or § 314.98, or that the applicant has refused to permit access to, or copying or verification of, its records.

(2) That on the basis of new information before FDA, evaluated together with the evidence available when the application or abbreviated application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to ensure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the agency.

(3) That on the basis of new information before FDA, evaluated together with the evidence available when the application or abbreviated application was approved, the labeling of the drug, based on a fair evaluation of all material facts, is false or misleading in any particular, and the labeling was not corrected by the applicant within a reasonable time after receipt of written notice from the agency.

(4) That the applicant has failed to comply with the notice requirements of section 510(j)(2) of the act.

(5) That the applicant has failed to submit bioavailability or bioequivalence data required under part 320 of this chapter.

(6) The application or abbreviated application does not contain an explanation of the omission of a report of any investigation of the drug product sponsored by the applicant, or an explanation of the omission of other information about the drug pertinent to an evaluation of the application or abbreviated application that is received or otherwise obtained by the applicant from any source.

(7) That any nonclinical laboratory study that is described in the application or abbreviated application and that is essential to show that the drug is safe for use under the conditions prescribed, recommended, or suggested in its labeling was not conducted in compliance with the good laboratory practice regulations in part 58 of this chapter and no reason for the noncompliance was provided or, if it was, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study.

(8) Any clinical investigation involving human subjects described in the application or abbreviated application, subject to the institutional review board regulations in part 56 of this chapter or informed consent regulations in part 50 of this chapter, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected.

(9) That the applicant or contract research organization that conducted a bioavailability or bioequivalence study contained in the application or abbreviated application refuses to permit an inspection of facilities or records relevant to the study by a properly authorized officer or employee

of the Department of Health and Human Services or refuses to submit reserve samples of the drug products used in the study when requested by FDA.

(10) That the labeling for the drug product that is the subject of the abbreviated new drug application is no longer consistent with that for the listed drug referred to in the abbreviated new drug application, except for differences approved in the abbreviated new drug application or those differences resulting from:

(i) A patent on the listed drug issued after approval of the abbreviated new drug application; or

(ii) Exclusivity accorded to the listed drug after approval of the abbreviated new drug application that do not render the drug product less safe or effective than the listed drug for any remaining, nonprotected condition(s) of use.

(c) FDA will withdraw approval of an application or abbreviated application if the applicant requests its withdrawal because the drug subject to the application or abbreviated application is no longer being marketed, provided none of the conditions listed in paragraphs (a) and (b) of this section applies to the drug. FDA will consider a written request for a withdrawal under this paragraph to be a waiver of an opportunity for hearing otherwise provided for in this section. Withdrawal of approval of an application or abbreviated application under this paragraph is without prejudice to refiling.

(d) FDA may notify an applicant that it believes a potential problem associated with a drug is sufficiently serious that the drug should be removed from the market and may ask the applicant to waive the opportunity for hearing otherwise provided for under this section, to permit FDA to withdraw approval of the application or abbreviated application for the product, and to remove voluntarily the product from the market. If the applicant agrees, the agency will not make a finding under paragraph (b) of this section, but will withdraw approval of the application or abbreviated application in a notice published in the **Federal Register** that contains a brief summary of the agency's and the applicant's views of the reasons for withdrawal.

36. New § 314.151 is added to subpart D to read as follows:

§ 314.151 Withdrawal of approval of an abbreviated new drug application under section 505(j)(5) of the act.

(a) Approval of an abbreviated new drug application approved under § 314.105(d) may be withdrawn when the agency withdraws approval, under § 314.150(a) or under this section, of the approved drug referred to in the abbreviated new drug application. If the agency proposed to withdraw approval of a listed drug under § 314.150(a), the holder of an approved application for the listed drug has a right to notice and opportunity for hearing. The published notice of opportunity for hearing will identify all drug products approved under § 314.105(d) whose applications are subject to withdrawal under this section if the listed drug is withdrawn, and will propose to withdraw such drugs. Holders of approved applications for the identified drug products will be provided notice and an opportunity to respond to the proposed withdrawal of their applications as described in paragraphs (b) and (c) of this section.

(b)(1) The published notice of opportunity for hearing on the withdrawal of the listed drug will serve as notice to holders of identified abbreviated new drug applications of the grounds for the proposed withdrawal.

(2) Holders of applications for drug products identified in the notice of opportunity for hearing may submit written comments on the notice of opportunity for hearing issued on the proposed withdrawal of the listed drug. If an abbreviated new drug application holder submits comments on the notice of opportunity for hearing and a hearing is granted, the abbreviated new drug application holder may participate in the hearing as a nonparty participant as provided for in § 12.89 of this chapter.

(3) Except as provided in paragraphs (c) and (d) of this section, the approval of an abbreviated new drug application for a drug product identified in the notice of opportunity for hearing on the withdrawal of a listed drug will be withdrawn when the agency has completed the withdrawal of approval of the listed drug.

(c)(1) If the holder of an application for a drug identified in the notice of opportunity for hearing has submitted timely comments but does not have an opportunity to participate in a hearing because a hearing is not requested or is settled, the submitted comments will be considered by the agency, which will issue an initial decision. The initial decision will respond to the comments, and contain the agency's decision whether there are grounds to withdraw approval of the listed drug and of the abbreviated new drug applications on which timely comments were submitted. The initial decision will be sent to each abbreviated new drug application holder that has submitted comments.

(2) Abbreviated new drug application holders to whom the initial decision was sent may, within 30 days of the issuance of the initial decision, submit written objections.

(3) The agency may, at its discretion, hold a limited oral hearing to resolve dispositive factual issues that cannot be resolved on the basis of written submissions.

(4) If there are no timely objections to the initial decision, it will become final at the expiration of 30 days.

(5) If timely objections are submitted, they will be reviewed and responded to in a final decision.

(6) The written comments received, the initial decision, the evidence relied on in the comments and in the initial decision, the objections to the initial decision, and, if a limited oral hearing has been held, the transcript of that hearing and any documents submitted therein, shall form the record upon which the agency shall make a final decision.

(7) Except as provided in paragraph (d) of this section, any abbreviated new drug application whose holder submitted comments on the notice of opportunity for hearing shall be withdrawn upon the issuance of a final decision concluding that the listed drug should be withdrawn for grounds as described in § 314.150(a). The final decision shall be in writing and shall constitute final agency action, reviewable in a judicial proceeding.

(8) Documents in the record will be publicly available in accordance with § 10.20(j) of this chapter. Documents available for examination or copying will be placed on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration, room. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, promptly upon receipt in that office.

(d) If the agency determines, based upon information submitted by the holder of an abbreviated new drug application, that the grounds for withdrawal of the listed drug are not applicable to a drug identified in the notice of opportunity for hearing, the final decision will state that the approval of the abbreviated new drug application for such drug is not withdrawn.

37. Section 314.152 is revised to read as follows:

§ 314.152 Notice of withdrawal of approval of an application or abbreviated application for a new drug.

If the Food and Drug Administration withdraws approval of an application or abbreviated application for a new drug, FDA will publish a notice in the **Federal Register** announcing the withdrawal of

approval. If the application or abbreviated application was withdrawn for grounds described in § 314.150(a) or § 314.151, the notice will announce the removal of the drug from the list of approved drugs published under section 505(j)(6) of the act and shall satisfy the requirement of § 314.162(b).

38. New § 314.153 is added to Subpart D to read as follows:

§ 314.153 Suspension of approval of an abbreviated new drug application.

(a) *Suspension of approval.* The approval of an abbreviated new drug application approved under § 314.105(d) shall be suspended for the period stated when:

(1) The Secretary of the Department of Health and Human Services, under the imminent hazard authority of section 505(e) of the act or the authority of this paragraph, suspends approval of a listed drug referred to in the abbreviated new drug application, for the period of the suspension;

(2) The agency, in the notice described in paragraph (b) of this section, or in any subsequent written notice given an abbreviated new drug application holder by the agency, concludes that the risk of continued marketing and use of the drug is inappropriate, pending completion of proceedings to withdraw or suspend approval under § 314.151 or paragraph (b) of this section; or

(3) The agency, under the procedures set forth in paragraph (b) of this section, issues a final decision stating the determination that the abbreviated application is suspended because the listed drug on which the approval of the abbreviated new drug application depends has been withdrawn from sale for reasons of safety or effectiveness or has been suspended under paragraph (b) of this section. The suspension will take effect on the date stated in the decision and will remain in effect until the agency determines that the marketing of the drug has resumed or that the withdrawal is not for safety or effectiveness reasons.

(b) *Procedures for suspension of abbreviated new drug applications when a listed drug is voluntarily withdrawn for safety or effectiveness reasons.* (1) If a listed drug is voluntarily withdrawn from sale, and the agency determines that the withdrawal from sale was for reasons of safety or effectiveness, the agency will send each holder of an approved abbreviated new drug application that is subject to suspension as a result of this determination a copy of the agency's initial decision setting forth the reasons for the determination. The initial decision will also be placed on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, room 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

(2) Each abbreviated new drug application holder will have 30 days from the issuance of the initial decision to present, in writing, comments and information bearing on the initial decision. If no comments or information is received, the initial decision will become final at the expiration of 30 days.

(3) Comments and information received within 30 days of the issuance of the initial decision will be considered by the agency and responded to in a final decision.

(4) The agency may, in its discretion, hold a limited oral hearing to resolve dispositive factual issues that cannot be resolved on the basis of written submissions.

(5) If the final decision affirms the agency's initial decision that the listed drug was withdrawn for reasons of safety or effectiveness, the decision will be published in the **Federal Register** in compliance with § 314.152, and will, except as provided in paragraph (b)(6) of this section, suspend approval of all abbreviated new drug applications identified under paragraph (b)(1) of this section and remove from the list the listed drug and any drug whose approval was suspended under this paragraph. The notice will satisfy the requirement of § 314.162(b). The agency's final decision and copies of materials on which it relies will also be filed with the Dockets Management Branch (address in paragraph (b)(1) of this section).

(6) If the agency determines in its final decision that the listed drug was withdrawn for reasons of safety or effectiveness but, based upon information submitted by the holder of an abbreviated new drug application, also determines that the reasons for the withdrawal of the listed drug are not relevant to the safety and effectiveness of the drug subject to such abbreviated new drug application, the final decision will state that the approval of such abbreviated new drug application is not suspended.

(7) Documents in the record will be publicly available in accordance with § 10.20(j) of this chapter. Documents available for examination or copying will be placed on public display in the Dockets Management Branch (address in paragraph (b)(1) of this section) promptly upon receipt in that office.

39. Section 314.160 is revised to read as follows:

§ 314.160 Approval of an application or abbreviated application for which approval was previously refused, suspended, or withdrawn.

Upon the Food and Drug Administration's own initiative or upon request of an applicant, FDA may, on the basis of new data, approve an application or abbreviated application which it had previously refused, suspended, or withdrawn approval. FDA will publish a notice in the **Federal Register** announcing the approval.

40. New §§ 314.161 and 314.162 are added to subpart D to read as follows:

§ 314.161 Determination of reasons for voluntary withdrawal of a listed drug.

(a) A determination whether a listed drug that has been voluntarily withdrawn from sale was withdrawn for safety or effectiveness reasons may be made by the agency at any time after the drug has been voluntarily withdrawn from sale, but must be made:

(1) Prior to approving an abbreviated new drug application that refers to the listed drug;

(2) Whenever a listed drug is voluntarily withdrawn from sale and abbreviated new drug applications that referred to the listed drug have been approved; and

(3) When a person petitions for such a determination under §§ 10.25(a) and 10.30 of this chapter.

(b) Any person may petition under §§ 10.25(a) and 10.30 of this chapter for a determination whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons. Any such petition must contain all evidence available to the petitioner concerning the reason that the drug is withdrawn from sale.

(c) If the agency determines that a listed drug is withdrawn from sale for safety or effectiveness reasons, the agency will, except as provided in paragraph (d) of this section, publish a notice of the determination in the **Federal Register.**

(d) If the agency determines under paragraph (a) of this section that a listed drug is withdrawn from sale for safety and effectiveness reasons and there are approved abbreviated new drug applications that are subject to suspension under section 505(j)(5) of the act, FDA will initiate a proceeding in accordance with § 314.153(b).

(e) A drug that the agency determines is withdrawn for safety or effectiveness reasons will be removed from the list, under § 314.162. The drug may be relisted if the agency has evidence that marketing of the drug has resumed or that the withdrawal is not for safety or

effectiveness reasons. A determination that the drug is not withdrawn for safety or effectiveness reasons may be made at any time after its removal from the list, upon the agency's initiative, or upon the submission of a petition under §§ 10.25(a) and 10.30 of this chapter. If the agency determines that the drug is not withdrawn for safety or effectiveness reasons, the agency shall publish a notice of this determination in the **Federal Register**. The notice will also announce that the drug is relisted, under § 314.162(c). The notice will also serve to reinstate approval of all suspended abbreviated new drug applications that referred to the listed drug.

§ 314.162 Removal of a drug product from the list.

(a) FDA will remove a previously approved new drug product from the list for the period stated when:

(1) The agency withdraws or suspends approval of a new drug application or an abbreviated new drug application under § 314.150(a) or § 314.151 or under the imminent hazard authority of section 505(e) of the act, for the same period as the withdrawal or suspension of the application; or

(2) The agency, in accordance with the procedures in § 314.153(b) or § 314.161, issues a final decision stating that the listed drug was withdrawn from sale for safety or effectiveness reasons, or suspended under § 314.153(b), until the agency determines that the withdrawal from the market has ceased or is not for safety or effectiveness reasons.

(b) FDA will publish in the **Federal Register** a notice announcing the removal of a drug from the list.

(c) At the end of the period specified in paragraph (a)(1) or (a)(2) of this section, FDA will relist a drug that has been removed from the list. The agency will publish in the **Federal Register** a notice announcing the relisting of the drug.

41. Section 314.200 is amended by revising the introductory text of paragraph (a), paragraphs (b)(1) and (b)(2), the last sentence in paragraph (c)(1), paragraph (c)(3), and the first sentence in paragraph (g)(1) to read as follows:

§ 314.200 Notice of opportunity for hearing; notice of participation and request for hearing; grant or denial of hearing.

(a) *Notice of opportunity for hearing.* The Director of the Center for Drug Evaluation and Research, Food and Drug Administration, will give the applicant, and all other persons who manufacture or distribute identical, related, or similar drug products as defined in § 310.6 of this chapter, notice and an opportunity for a hearing on the Center's proposal to refuse to approve an application or to withdraw the approval of an application or abbreviated application under section 505(e) of the act. The notice will state the reasons for the action and the proposed grounds for the order.

* * * * *

(b) * * *

(1) To any person who has submitted an application or abbreviated application, by delivering the notice in person or by sending it by registered or certified mail to the last address shown in the application or abbreviated application.

(2) To any person who has not submitted an application or abbreviated application but who is subject to the notice under § 310.6 of this chapter, by publication of the notice in the **Federal Register**.

(c)(1) * * * The applicant, or other person, may incorporate by reference the raw data underlying a study if the data were previously submitted to FDA as part of an application, abbreviated application, or other report.

* * * * *

(3) Any other interested person who is not subject to the notice of opportunity for a hearing may also submit comments on the proposal to withdraw approval of the application or abbreviated application. The comments are requested to be submitted within the time and under the conditions specified in this section.

* * * * *

(g) * * *

(1) Where a specific notice of opportunity for hearing (as defined in paragraph (a)(1) of this section) is used, the Commissioner will enter summary judgment against a person who requests a hearing, making findings and conclusions, denying a hearing, if it conclusively appears from the face of the data, information, and factual analyses in the request for the hearing that there is no genuine and substantial issue of fact which precludes the refusal to approve the application or abbreviated application or the withdrawal of approval of the application or abbreviated application; for example, no adequate and well-controlled clinical investigations meeting each of the precise elements of § 314.126 and, for a combination drug product, § 300.50 of this chapter, showing effectiveness have been identified. * * *

* * * * *

42. Section 314.430 is amended by revising the section heading, paragraphs (a), (b), (c), and (d), the introductory text of paragraph (e), paragraphs (f)(5) and (f)(6), and the introductory text of paragraph (g) to read as follows:

§ 314.430 Availability for public disclosure of data and information in an application or abbreviated application.

(a) The Food and Drug Administration will determine the public availability of any part of an application or abbreviated application under this section and part 20 of this chapter. For purposes of this section, the application or abbreviated application includes all data and information submitted with or incorporated by reference in the application or abbreviated application, including investigational new drug applications, drug master files under § 314.420, supplements submitted under § 314.70 or § 314.97, reports under § 314.80 or § 314.98, and other submissions. For purposes of this section, safety and effectiveness data include all studies and tests of a drug on animals and humans and all studies and tests of the drug for identity, stability, purity, potency, and bioavailability.

(b) FDA will not publicly disclose the existence of an application or abbreviated application before an approvable letter is sent to the applicant under § 314.110, unless the existence of the application or abbreviated application has been previously publicly disclosed or acknowledged. The Center for Drug Evaluation and Research will maintain and make available for public disclosure a list of applications or abbreviated applications for which the agency has sent an approvable letter to the applicant.

(c) If the existence of an unapproved application or abbreviated application has not been publicly disclosed or acknowledged, no data or information in the application or abbreviated application is available for public disclosure.

(d) If the existence of an application or abbreviated application has been publicly disclosed or acknowledged before the agency sends an approval letter to the applicant, no data or information contained in the application or abbreviated application is available for public disclosure before the agency sends an approval letter, but the Commissioner may, in his or her discretion, disclose a summary of selected portions of the safety and effectiveness data that are appropriate for public consideration of a specific pending issue; for example, for consideration of an open session of an FDA advisory committee.

(e) After FDA sends an approval letter to the applicant, the following data and information in the application or abbreviated application are immediately available for public disclosure, unless the applicant shows that extraordinary circumstances exist. A list of approved applications and abbreviated applications, entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," is available from the Government Printing Office, Washington, DC 20402. This list is updated monthly.

* * * * *

(f) * * *

(5) For applications submitted under section 505(b) of the act, the effective date of the approval of the first abbreviated application submitted under section 505(j) of the act which refers to such drug, or the date on which the approval of an abbreviated application under section 505(j) of the act which refers to such drug could be made effective if such an abbreviated application had been submitted.

(6) For applications or abbreviated applications submitted under sections 505(j), 506, and 507 of the act, when FDA sends an approval letter to the applicant.

(g) The following data and information in an application or abbreviated application are not available for public disclosure unless they have been previously disclosed to the public as set forth in § 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they do not represent a trade secret or confidential commercial or financial information under § 20.61 of this chapter:

* * * * *

43. Section 314.440 is amended by revising the section heading, the introductory text of paragraph (a), and paragraphs (a)(1) and (a)(2) to read as follows:

§ 314.440 Addresses for applications and abbreviated applications.

(a) Applicants shall send applications, abbreviated applications, and other correspondence relating to matters covered by this part, except for products listed in paragraph (b) of this section, to the Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, and directed to the appropriate office identified below:

(1) An application under § 314.50 or § 314.54 submitted for filing should be directed to the Document and Records Section, 12420 Parklawn Dr., Rockville, MD 20852. Applicants may obtain folders for binding applications from the Forms and Publications Warehouse, 12100 Parklawn Dr., Rockville, MD 20852. After FDA has filed the application, the agency will inform the applicant which division is responsible for the application. Amendments, supplements, resubmissions, requests for waivers, and other correspondence about an application that has been filed should be directed to the appropriate division.

(2) An abbreviated application under § 314.94, and amendments, supplements, and resubmissions should be directed to the Office of Generic Drugs (HFD–600), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Items sent by parcel post or overnight courier service should be directed to the Office of Generic Drugs (HFD–600), Center for Drug Evaluation and Research, Food and Drug Administration, Metro Park North II, 7500 Standish Place, rm. 150, Rockville, MD 20855. Correspondence not associated with an application should be addressed specifically to the intended office or division and to the person as follows: Center for Drug Evaluation and Research, Food and Drug Administration, Attn: [*insert name of person*], MPN II, HFD–[*insert mail code of office or division*], 5600 Fishers Lane, Rockville, MD 20857. The mail code for the Office of Generic Drugs is HFD–600, the mail code for the Division of Chemistry is HFD–630, and the mail code for the Division of Bioequivalence is HFD–650.

* * * * *

PART 320—BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

44. Part 320 is amended by revising the table of contents with the authority citation continuing to read as follows:

PART 320—BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

Subpart A—General Provisions

Sec.
320.1 Definitions.

Subpart B—Procedures for Determining the Bioavailability or Bioequivalence of Drug Products

320.21 Requirements for submission of in vivo bioavailability and bioequivalence data.
320.22 Criteria for waiver of evidence of in vivo bioavailability or bioequivalence.
320.23 Basis for demonstrating in vivo bioavailability or bioequivalence.
320.24 Types of evidence to establish bioavailability or bioequivalence.
320.25 Guidelines for the conduct of an in vivo bioavailability study.
320.26 Guidelines on the design of a single-dose in vivo bioavailability study.
320.27 Guidelines on the design of a multiple-dose in vivo bioavailability study.
320.28 Correlation of bioavailability with an acute pharmacological effect or clinical evidence.
320.29 Analytical methods for an in vivo bioavailability study.
320.30 Inquiries regarding bioavailability and bioequivalence requirements and review of protocols by the Food and Drug Administration.
320.31 Applicability of requirements regarding an "Investigational New Drug Application."
320.32 Procedures for establishing or amending a bioequivalence requirement.
320.33 Criteria and evidence to assess actual or potential bioequivalence problems.
320.34 Requirements for batch testing and certification by the Food and Drug Administration.
320.35 Requirements for in vitro testing of each batch.
320.36 Requirements for maintenance of records of bioequivalence testing.
320.38 Retention of bioavailability samples.
320.63 Retention of bioequivalence samples.

Authority: Secs. 201, 501, 502, 505, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 355, 357, 371).

45. Section 320.1 is amended by revising paragraphs (a) and (e) to read as follows:

§ 320.1 Definitions.

(a) *Bioavailability* means the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of action. For drug products that are not intended to be absorbed into the bloodstream, bioavailability may be assessed by measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of action.

* * * * *

(e) *Bioequivalence* means the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. Where there is an intentional difference in rate (e.g., in certain controlled release dosage forms), certain pharmaceutical equivalents or alternatives may be considered bioequivalent if there is no significant difference in the extent to which the active ingredient or moiety from each product becomes available at the site of drug action. This applies only if the difference in the rate at which the active

ingredient or moiety becomes available at the site of drug action is intentional and is reflected in the proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

* * * * *

46. Part 320 is amended by revising the heading for subpart B, revising §§ 320.21, 320.22, 320.23, 320.24, 320.30, and 320.31, and by removing the heading for subpart C to read as follows:

Subpart B—Procedures for Determining the Bioavailability or Bioequivalence of Drug Products

§ 320.21 Requirements for submission of in vivo bioavailability and bioequivalence data.

(a) Any person submitting a full new drug application to the Food and Drug Administration (FDA) shall include in the application either:

(1) Evidence demonstrating the in vivo bioavailability of the drug product that is the subject of the application; or

(2) Information to permit FDA to waive the submission of evidence demonstrating in vivo bioavailability.

(b) Any person submitting an abbreviated new drug application to FDA shall include in the application either:

(1) Evidence demonstrating that the drug product that is the subject of the abbreviated new drug application is bioequivalent to the reference listed drug (defined in § 314.3(b)); or

(2) Information to show that the drug product is bioequivalent to the reference listed drug which would permit FDA to waive the submission of evidence demonstrating bioequivalence as provided in paragraph (f) of this section.

(c) Any person submitting a supplemental application to FDA shall include in the supplemental application the evidence or information set forth in paragraphs (a) and (b) of this section if the supplemental application proposes any of the following changes:

(1) A change in the manufacturing process, including a change in product formulation or dosage strength, beyond the variations provided for in the approved application.

(2) A change in the labeling to provide for a new indication for use of the drug product, if clinical studies are required to support the new indication for use.

(3) A change in the labeling to provide for a new dosage regimen or for an additional dosage regimen for a special patient population, e.g., infants, if clinical studies are required to support the new or additional dosage regimen.

(d) FDA may approve a full new drug application, or a supplemental application proposing any of the changes set forth in paragraph (c) of this section, that does not contain evidence of in vivo bioavailability or information to permit waiver of the requirement for in vivo bioavailability data, if all of the following conditions are met.

(1) The application was under review by FDA on July 7, 1977.

(2) The application is otherwise approvable.

(3) The application agrees to submit, within the time specified by FDA, either:

(i) Evidence demonstrating the in vivo bioavailability of the drug product that is the subject of the application; or

(ii) Information to permit FDA to waive demonstration of in vivo bioavailability.

(e) Evidence demonstrating the in vivo bioavailability and bioequivalence of a drug product shall be obtained using one of the approaches for determining bioavailability set forth in § 320.24.

(f) Information to permit FDA to waive the submission of evidence demonstrating the in vivo bioavailability or bioequivalence shall meet the criteria set forth in § 320.24.

(g) Any person holding an approved full or abbreviated new drug application shall submit to FDA a supplemental application containing new evidence demonstrating the in vivo bioavailability or bioequivalence of the drug product that is the subject of the application if notified by FDA that:

(1) There are data demonstrating that the dosage regimen in the labeling is based on incorrect assumptions or facts regarding the pharmacokinetics of the drug product and that following this dosage regimen could potentially result in subtherapeutic or toxic levels; or

(2) There are data demonstrating significant intra-batch and batch-to-batch variability, e.g., plus or minus 25 percent, in the bioavailability of the drug product.

(h) The requirements of this section regarding the submission of evidence demonstrating in vivo bioavailability and bioequivalence apply only to a full or abbreviated new drug application or a supplemental application for a finished dosage formulation.

§ 320.22 Criteria for waiver of evidence of in vivo bioavailability or bioequivalence.

(a) Any person submitting a full or abbreviated new drug application, or a supplemental application proposing any of the changes set forth in § 320.21(c), may request FDA to waive the requirement for the submission of evidence demonstrating the in vivo bioavailability or bioequivalence of the drug product that is the subject of the application. An applicant shall submit a request for waiver with the application. Except as provided in paragraph (g) of this section, FDA shall waive the requirement for the submission of evidence of in vivo bioavailability or bioequivalence if the drug product meets any of the provisions of paragraphs (b), (c), (d), or (e) of this section.

(b) For certain drug products, the in vivo bioavailability or bioequivalence of the drug product may be self-evident. FDA shall waive the requirement for the submission of evidence obtained in vivo demonstrating the bioavailability or bioequivalence of these drug products. A drug product's in vivo bioavailability or bioequivalence may be considered self-evident based on other data in the application if the product meets one of the following criteria:

(1) The drug product:

(i) Is a parenteral solution intended solely for administration by injection, or an ophthalmic or otic solution; and

(ii) Contains the same active and inactive ingredients in the same concentration as a drug product that is the subject of an approved full new drug application.

(2) The drug product:

(i) Is administered by inhalation as a gas, e.g., a medicinal or an inhalation anesthetic; and

(ii) Contains an active ingredient in the same dosage form as a drug product that is the subject of an approved full new drug application.

(3) The drug product:

(i) Is a solution for application to the skin, an oral solution, elixir, syrup, tincture, or similar other solubilized form.

(ii) Contains an active drug ingredient in the same concentration and dosage form as a drug product that is the subject of an approved full new drug application; and

(iii) Contains no inactive ingredient or other change in formulation from the drug product that is the subject of the approved full new drug application that may significantly affect absorption of the active drug ingredient or active moiety.

(c) FDA shall waive the requirement for the submission of evidence demonstrating the in vivo bioavailability of a solid oral dosage form (other than an enteric coated or controlled release dosage form) of a drug product determined to be effective for at least one indication in a Drug Efficacy Study Implementation notice or which is identical, related, or similar to such a drug product under § 310.6 of this chapter unless FDA has evaluated the

drug product under the criteria set forth in § 320.32, included the drug product in the Approved Drug Products with Therapeutic Equivalence Evaluations List, and rated the drug product as having a known or potential bioequivalence problem. A drug product so rated reflects a determination by FDA that an in vivo bioequivalence study is required.

(d) For certain drug products, bioavailability or bioequivalence may be demonstrated by evidence obtained in vitro in lieu of in vivo data. FDA shall waive the requirement for the submission of evidence obtained in vivo demonstrating the bioavailability of the drug product if the drug product meets one of the following criteria:

(1) [Reserved]

(2) The drug product is in the same dosage form, but in a different strength, and is proportionally similar in its active and inactive ingredients to another drug product for which the same manufacturer has obtained approval and the conditions in paragraphs (d)(2)(i) through (d)(2)(iii) of this section are met:

(i) The bioavailability of this other drug product has been demonstrated;

(ii) Both drug products meet an appropriate in vitro test approved by FDA; and

(iii) The applicant submits evidence showing that both drug products are proportionally similar in their active and inactive ingredients.

(iv) This subparagraph does not apply to enteric coated or controlled release dosage forms.

(3) The drug product is, on the basis of scientific evidence submitted in the application, shown to meet an in vitro test that has been correlated with in vivo data.

(4) The drug product is a reformulated product that is identical, except for a different color, flavor, or preservative that could not affect the bioavailability of the reformulated product, to another drug product for which the same manufacturer has obtained approval and the following conditions are met:

(i) The bioavailability of the other product has been demonstrated; and

(ii) Both drug products meet an appropriate in vitro test approved by FDA.

(e) FDA, for good cause, may waive a requirement for the submission of evidence of in vivo bioavailability if waiver is compatible with the protection of the public health. For full new drug applications, FDA may defer a requirement for the submission of evidence of in vivo bioavailability if deferral is compatible with the protection of the public health.

(f) FDA, for good cause, may require evidence of in vivo bioavailability or bioequivalence for any drug product if the agency determines that any difference between the drug product and a listed drug may affect the bioavailability or bioequivalence of the drug product.

§ 320.23 Basis for demonstrating in vivo bioavailability or bioequivalence.

(a)(1) The in vivo bioavailability of a drug product is demonstrated if the product's rate and extent of absorption, as determined by comparison of measured parameters, e.g., concentration of the active drug ingredient in the blood, urinary excretion rates, or pharmacological effects, do not indicate a significant difference from the reference material's rate and extent of absorption. For drug products that are not intended to be absorbed into the bloodstream, bioavailability may be assessed by measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of action.

(2) Statistical techniques used shall be of sufficient sensitivity to detect differences in rate and extent of absorption that are not attributable to subject variability.

(3) A drug product that differs from the reference material in its rate of absorption, but not in its extent of absorption, may be considered to be bioavailable if the difference in the rate of absorption is intentional, is appropriately reflected in the labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug product.

(b) Two drug products will be considered bioequivalent drug products if they are pharmaceutical equivalents or pharmaceutical alternatives whose rate and extent of absorption do not show a significant difference when administered at the same molar dose of the active moiety under similar experimental conditions, either single dose or multiple dose. Some pharmaceutical equivalents or pharmaceutical alternatives may be equivalent in the extent of their absorption but not in their rate of absorption and yet may be considered bioequivalent because such differences in the rate of absorption are intentional and are reflected in the labeling, are not essential to the attainment of effective body drug concentrations on chronic use, and are considered medically insignificant for the particular drug product studied.

§ 320.24 Types of evidence to establish bioavailability or bioequivalence.

(a) Bioavailability or bioequivalence may be determined by several in vivo and in vitro methods. FDA may require in vivo or in vitro testing, or both, to establish the bioavailability of a drug product or the bioequivalence of specific drug products. Information on bioequivalence requirements for specific products is included in the current edition of FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations" and any current supplement to the publication. The selection of the method used to meet an in vivo or in vitro testing requirement depends upon the purpose of the study, the analytical methods available, and the nature of the drug product. Applicants shall conduct bioavailability and bioequivalence testing using the most accurate, sensitive, and reproducible approach available among those set forth in paragraph (b) of this section. The method used must be capable of demonstrating bioavailability or bioequivalence, as appropriate, for the product being tested.

(b) The following in vivo and in vitro approaches, in descending order of accuracy, sensitivity, and reproducibility, are acceptable for determining the bioavailability or bioequivalence of a drug product.

(1)(i) An in vivo test in humans in which the concentration of the active ingredient or active moiety, and, when appropriate, its active metabolite(s), in whole blood, plasma, serum, or other appropriate biological fluid is measured as a function of time. This approach is particularly applicable to dosage forms intended to deliver the active moiety to the bloodstream for systemic distribution within the body; or

(ii) An in vitro test that has been correlated with and is predictive of human in vivo bioavailability data; or

(iii) An in vivo test in animals that has been correlated with and is predictive of human bioavailability data.

(2) An in vivo test in humans in which the urinary excretion of the active moiety, and, when appropriate, its active metabolite(s), are measured as a function of time. The intervals at which measurements are taken should ordinarily be as short as possible so that the measure of the rate of elimination is as accurate as possible. Depending on the nature of the drug product, this approach may be applicable to the category of dosage forms described in paragraph (b)(1)(i) of this section. This method is not appropriate where urinary

excretion is not a significant mechanism of elimination.

(3) An in vivo test in humans in which an appropriate acute pharmacological effect of the active moiety, and, when appropriate, its active metabolite(s), are measured as a function of time if such effect can be measured with sufficient accuracy, sensitivity, and reproducibility. This approach is applicable to the category of dosage forms described in paragraph (b)(1)(i) of this section only when appropriate methods are not available for measurement of the concentration of the moiety, and, when appropriate, its active metabolite(s), in biological fluids or excretory products but a method is available for the measurement of an appropriate acute pharmacological effect. This approach may be particularly applicable to dosage forms that are not intended to deliver the active moiety to the bloodstream for systemic distribution.

(4) Well-controlled clinical trials in humans that establish the safety and effectiveness of the drug product, for purposes of establishing bioavailability, or appropriately designed comparative clinical trials, for purposes of demonstrating bioequivalence. This approach is the least accurate, sensitive, and reproducible of the general approaches for determining bioavailability or bioequivalence. For dosage forms intended to deliver the active moiety to the bloodstream for systemic distribution, this approach may be considered acceptable only when analytical methods cannot be developed to permit use of one of the approaches outlined in paragraphs (b)(1)(i) and (b)(2) of this section, when the approaches described in paragraphs (b)(1)(ii), (b)(1)(iii), and (b)(3) of this section are not available. Ths approach may also be considered sufficiently accurate for determining the bioavailability or bioequivalence of dosage forms intended to deliver the active moiety locally, e.g., topical preparations for the skin, eye, and mucous membranes; oral dosage forms not intended to be absorbed, e.g., an antacid or radiopaque medium; and bronchodilators administered by inhalation if the onset and duration of pharmacological activity are defined.

(5) A currently available in vitro test acceptable to FDA (unusually a dissolution rate test) that ensures human in vivo bioavailability.

(6) Any other approach deemed adequate by FDA to establish bioavailability or bioequivalence.

(c) FDA may, notwithstanding prior requirements for establishing bioavailability or bioequivalence, require in vivo testing in humans of a product at any time if the agency has evidence that the product:

(1) May not produce therapeutic effects comparable to a pharmaceutical equivalent or alternative with which it is intended to be used interchangeably;

(2) May not be bioequivalent to a pharmaceutical equivalent or alternative with which it is intended to be used interchangeably; or

(3) Has greater than anticipated potential toxicity related to pharmacokinetic or other characteristics.

§ 320.30 Inquiries regarding bioavailability and bioequivalence requirements and review of protocols by the Food and Drug Administration.

(a) The Commissioner of Food and Drugs strongly recommends that, to avoid the conduct of an improper study and unnecessary human research, any person planning to conduct a bioavailability or bioequivalence study submit the proposed protocol for the study to FDA for review prior to the initiation of the study.

(b) FDA may review a proposed protocol for a bioavailability or bioequivalence study and will offer advice with respect to whether the following conditions are met:

(1) The design of the proposed bioavailability or bioequivalence study is appropriate.

(2) The reference material to be used in the bioavailability or bioequivalence study is appropriate.

(3) The proposed chemical and statistical analytical methods are adequate.

(c)(1) General inquiries relating to in vivo bioavailability requirements and methodology shall be submitted to the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Biopharmaceutics (HFD–420), 5600 Fishers Lane, Rockville, MD 20857.

(2) General inquiries relating to bioequivalence requirements and methodology shall be submitted to the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Bioequivalence (HFD–650), 5600 Fishers Lane, Rockville, MD 20857.

§ 320.31 Applicability of requirements regarding an "Investigational New Drug Application."

(a) Any person planning to conduct an in vivo bioavailability or bioequivalence study in humans shall submit an "Investigational New Drug Application" (IND) if:

(1) The test product contains a new chemical entity as defined in § 314.108(a) of this chapter; or

(2) The study involves a radioactively labeled drug product; or

(3) The study involves a cytotoxic drug product.

(b) Any person planning to conduct a bioavailability study in humans using a drug product that contains an already approved, non-new chemical entity shall submit an IND if the study is one of the following:

(1) A single-dose study in normal subjects or patients where either the maximum single or total daily dose exceeds that specified in the labeling of the drug product that is the subject of an approved new drug application or abbreviated new drug application.

(2) A multiple-dose study in normal subjects or patients where either the single or total daily dose exceeds that specified in the labeling of the drug product that is the subject of an approved new drug application or abbreviated new drug application.

(3) A multiple-dose study on a controlled release product on which no single-dose study has been completed.

(c) The provisions of part 312 of this chapter are applicable to any bioavailability or bioequivalence study conducted under an IND.

(d) [Reserved]

(e) [Reserved]

(f) An in vivo bioavailability or bioequivalence study in humans shall be conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter, and informed consent set forth in part 50 of this chapter, regardless of whether the study is conducted under an IND.

§ 320.32 [Redesignated as § 320.38]

47. Section 320.32 *Retention of bioavailability samples* is redesignated as § 320.38.

§ 320.50 [Removed]

48. Section 320.50 *Purpose* is removed.

§ 320.51 [Redesignated as § 320.32]

49. Section 320.51 is redesignated as § 320.32 in subpart B and is revised to read as follows:

§ 320.32 Procedures for establishing or amending a bioequivalence requirement.

(a) The Food and Drug Administration, on its own initiative or in response to a petition by an interested person, may propose and promulgate a regulation to establish a bioequivalence requirement for a product not subject to section 505(j) of the act if it finds there is well-documented evidence that specific

pharmaceutical equivalents or pharmaceutical alternatives intended to be used interchangeably for the same therapeutic effect:

(1) Are not bioequivalent drug products; or

(2) May not be bioequivalent drug products based on the criteria set forth in § 320.33; or

(3) May not be bioequivalent drug products because they are members of a class of drug products that have close structural similarity and similar physicochemical or pharmacokinetic properties to other drug products in the same class that FDA finds are not bioequivalent drug products.

(b) FDA shall include in a proposed rule to establish a bioequivalence requirement the evidence and criteria set forth in § 320.33 that are to be considered in determining whether to issue the proposal. If the rulemaking is proposed in response to a petition, FDA shall include in the proposal a summary and analysis of the relevant information that was submitted in the petition as well as other available information to support the establishment of a bioequivalence requirement.

(c) FDA, on its own initiative or in response to a petition by an interested person, may propose and promulgate an amendment to a bioequivalence requirement established under this subpart.

§ 320.52 [Redesignated as § 320.33]

50. Section 320.52 is redesignated as § 320.33 in subpart B, and the section heading and the introductory paragraph are revised to read as follows:

§ 320.33 Criteria and evidence to assess actual or potential bioequivalence problems.

The Commissioner of Food and Drugs shall consider the following factors, when supported by well-documented evidence, to identify specific pharmaceutical equivalents and pharmaceutical alternatives that are not or may not be bioequivalent drug products.

* * * * *

§ 320.53 [Removed]

51. Section 320.53 *Types of bioequivalence requirements* is removed.

§ 320.54 [Removed]

52. Section 320.54 *Contents of a petition to establish a bioequivalence requirement* is removed.

§§ 320.55 and 320.56 [Redesignated as §§ 320.34 and 320.35]

53. Section 320.55 *Requirements for batch testing and certification by the Food and Drug Administration* and § 320.56 *Requirements for in vitro testing of each batch* are redesignated as §§ 320.34 and 320.35 in subpart B, respectively.

§ 320.57 [Removed]

54. Section 320.57 *Requirements for the conduct of in vivo bioequivalence testing in humans* is removed.

§ 320.58 [Removed]

55. Section 320.58 *Requirements for marketing a drug product subject to a bioequivalence requirement* is removed.

§ 320.59 [Removed]

56. Section 320.59 *Bioequivalence requirements based on data voluntarily submitted* is removed.

§ 320.60 [Removed]

57. Section 320.60 *Bioequivalence requirements for a drug product subject to an old drug monograph* is removed.

§ 320.61 [Removed]

58. Section 320.61 *Requirements for in vivo testing of a drug product not meeting an in vitro bioequivalance standard is removed.*

§ 320.62 [Redesignated as § 320.36]

59. Section 320.62 *Requirements for maintenance of records of bioequivalence testing* is redesignated as § 320.36 in subpart B.

PART 433—EXEMPTIONS FROM ANTIBIOTIC CERTIFICATION AND LABELING REQUIREMENTS

60. The authority citation for 21 CFR part 433 continues to read as follows:

Authority: Secs. 502, 505, 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 355, 357).

§ 433.1 [Amended]

61. Section 433.1 *Exemption of antibiotic drugs for human use from batch certification requirements* is amended in paragraph (d)(2) by removing "§ 314.55" and replacing it with "§ 314.94".

Dated: July 17, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

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Part III

Securities and Exchange Commission

17 CFR Parts 230 and 240

Penny Stock Transactions; Final Rules, Proposed Rule, and Notice

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 240

[Release No. 34-30608]

RIN 3235-AE21

Penny Stock Disclosure Rules

AGENCY: Securities and Exchange Commission.

ACTION: Final rules.

SUMMARY: The Commission is adopting seven rules ("Rules") under the Securities Exchange Act of 1934 ("Exchange Act") requiring broker-dealers engaging in transactions in low-priced, over-the-counter securities, often referred to as "penny stocks," with or for their customers to provide to those customers certain specified information. Unless one of various exemptions is available, the Rules require broker-dealers effecting customer transactions in penny stocks, as defined by the Rules, to provide the customers with: A risk disclosure document; disclosure of market quotations, if any; disclosure of the compensation of the broker-dealer and its salesperson in the transaction; and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotation and compensation information must be provided prior to effecting the transaction and must be contained on the customer's confirmation. These Rules are being adopted pursuant to the requirements of the Securities Enforcement Remedies and Penny Stock Reform Act of 1990 ("Penny Stock Act").

EFFECTIVE DATE: Sections 240.3a51-1 and 240.15g-1 will be effective on April 28, 1992. The effective date for §§ 240.15g-2 and 240.15g-100 is July 15, 1992. The effective date for §§ 240.15g-3, 240.15g-4, 240.15g-5, and 240.15g-6 is January 1, 1993.

FOR FURTHER INFORMATION CONTACT: Robert L. D. Colby, Chief Counsel; John M. Ramsay, Branch Chief (with respect to Rules 15g-5 and 15g-6); Belinda Blaine, Attorney (with respect to Rules 3a51-1 and 15g-1); or Alexander Dill, Attorney (with respect to Rule 15g-2 and Schedule 15G, Rule 15g-3, and Rule 15g-4); all at (202) 504-2418, Office of Chief Counsel, Division of Market Regulation, Securities and Exchange Commission, 450 Fifth Street NW., Mail Stop 5-1, Washington, DC 20549.

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I. Executive Summary

The Commission is adopting the Rules in order to implement certain provisions of the Penny Stock Act and section 15(g) [1] of the Exchange Act. Rules concerning these matters were proposed in Securities Exchange Act Release No. 29093 (April 17, 1991), 56 FR 19165 (the "Proposing Release"). The Commission has determined not to adopt at this time proposed Rule 15g-7, which would have required disclosure of the status of a broker-dealer as a sole market maker in connection with penny stock transactions. Specific provisions of each of the adopted Rules are summarized below.

[1] 15 U.S.C. 78o(g).

Rule 3a51-1—Definition of "Penny Stock"

Rule 3a51-1 implements the provisions of section 3(a)(51) of the Exchange Act by defining the term "penny stock" to exclude certain equity securities. In general, Rule 3a51-1 excludes from the definition of penny stock any security that is a "reported security," [2] except that a security that is registered on the American Stock Exchange, Inc. ("Amex") pursuant to the listing criteria of the Emerging Company Marketplace ("ECM") is considered to be a "penny stock" solely for purposes of section 15(b)(6) of the Exchange Act. Securities listed on the New York Stock Exchange, Inc. ("NYSE") and Amex (other than ECM securities), as well as securities that meet NYSE or Amex listing standards but that are listed only on the regional exchanges, are reported securities for purposes of the rule. In addition, securities quoted on the National Association of Securities Dealers, Inc.'s ("NASD") automated quotation system ("NASDAQ") that are designated as National Market System ("NMS") securities are reported securities pursuant to Rule 11Aa3-1 of the Exchange Act.

Paragraph (e) of Rule 3a51-1 also excludes from the definition of penny stock for most purposes any security that is registered, or approved for registration upon notice of issuance, on a national securities exchange that makes transaction reports available pursuant to Rule 11Aa3-1, provided that: (1) Current price and volume information with respect to transactions in that security is required to be reported and is made available to vendors pursuant to the rules of the national securities exchange; and (2) the security is purchased or sold in a transaction on or through the facilities of a national securities exchange, or as part of a distribution of the security. The rule contains a similar provision excluding any security that is authorized, or approved for authorization upon notice of issuance, for quotation on NASDAQ. This exclusion is subject to the condition that current price and volume information with respect to transactions in that security must be reported and be made available to vendors pursuant to the rules of the NASD.

Rule 3a51-1 further defines the term "penny stock" to exclude securities that have a price of five dollars or more (including any share of any unit that has

[2] *i.e.*, securities for which last sale reports are collected and made available pursuant to an effective transaction reporting plan.

an independent exercise price), as determined either on a per transaction basis or, in the absence of a transaction, on the basis of the inside bid quotation for the security displayed on an automated quotation system that has the characteristics set forth in section 17B(b)(2) of the Exchange Act or any other system that is designated by the Commission for purposes of the rule ("Qualifying Electronic Quotation System"). If there is no such inside bid quotation, price is determined by the average of three or more interdealer bid quotations at specified prices displayed in an interdealer quotation system, as defined in Rule 15c2-7(c)(1), by three or more market makers in the security.

Paragraph (g) of Rule 3a51-1 excludes from the definition of penny stock securities whose issuer has either (1) net tangible assets in excess of $2 million, if that issuer has been in continuous operation for at least three years, or $5 million, if the issuer has been in continuous operation for less than three years; or (2) average revenue of at least $6 million for the last three years.[3] The required level of net tangible assets or revenues must be demonstrated by current, audited financial statements that the broker-dealer has reviewed and has a reasonable basis for believing are accurate.

Finally, Rule 3a51-1 excludes from the definition of penny stock securities that are issued by an investment company registered under the Investment Company Act of 1940 and put and call options issued by the Options Clearing Corporation ("OCC").

Rule 15g-1—Exemptions

Rule 15g-1 exempts certain transactions from the broker-dealer disclosure requirements of Rules 15g-2 through 15g-6. First, Rule 15g-1 exempts transactions in penny stocks by broker-dealers that derive less than 5% of their revenues from sales of penny stocks during a specified period, unless they are acting as a market maker in the penny stock that is the subject of the transaction. Second, transactions in which the customer is an institutional accredited investor are exempt from Rules 15g-2 through 15g-6. Third, the rule exempts transactions that meet the requirements of Regulation D, or that are exempt from the registration requirements of the Securities Act of 1933 ("Securities Act") pursuant to section 4(2) of that Act. Fourth, transactions in which the customer is the issuer, or a director, officer, general partner, or direct or indirect beneficial owner of more than 5% of any class of equity security of the issuer, of the penny stock that is the subject of the transaction, are exempt from the Rules. Finally, the rule exempts transactions that are not recommended by the broker or dealer. Rule 15g-1 also contains a provision giving to the Commission the authority to exempt by order any other transactions or persons from the Rules, if such an exemption would be consistent with the public interest and the protection of investors.

Rule 15g-2—Risk Disclosure Document

Rule 15g-2 makes it unlawful for a broker-dealer to effect transactions in penny stocks without providing to the customer a standardized disclosure document as contained in Schedule 15G prior to such transactions. The first part of Schedule 15G is a one-page summary of the essential items required to be disclosed under section 15(g)(2). The remainder explains the required information in greater detail: The risks of investing in penny stocks in both public offerings and secondary trading; terms important to an understanding of the functioning of the penny stock market, such as "bid" and "offer" quotes, a dealer's "spread," and broker-dealer compensation; the broker-dealer's duties to its customers, including the disclosures required by the other penny stock disclosure rules, and the customer's rights and remedies in cases of fraud in penny stock transactions; and the NASD's toll-free number and the central number of the North American Securities Administrators Association ("NASAA") for information on the disciplinary history of broker-dealers and their associated persons.

Rule 15g-3—Bid-Offer Quotations

Rule 15g-3 makes it unlawful for a broker-dealer to effect a transaction in any penny stock without first disclosing and subsequently confirming to the customer current quotation prices or similar market information.

For transactions effected on a principal basis, the broker-dealer must provide the inside bid and offer quotations for a penny stock appearing on a Qualifying Electronic Quotation System. If this quotation information is unavailable, the rule requires that a broker-dealer effecting principal transactions in a penny stock must disclose its own bid and offer quotes in the stock to a customer if the broker-dealer has effected at least three *bona fide* interdealer transactions consistently at these bid or offer prices over the previous five business days, no less than 75% of these transactions have occurred consistently at such quotes, and the broker-dealer reasonably believes that such quotes accurately reflect the prices at which it is prepared to trade with other dealers. If the dealer cannot validate its own quotations in accordance with this procedure, the dealer must disclose that it has not traded consistently at its quotes, and it must disclose the price at which it last purchased the penny stock from, or sold the penny stock to, another dealer in a *bona fide* transaction.

In transactions effected on an agency or riskless principal basis, the broker-dealer must disclose the best interdealer bid and offer prices for the penny stock that the broker-dealer can obtain through reasonable diligence. For all transactions in penny stocks to which Rule 15g-3 applies, the broker-dealer must also disclose the number of shares for which the bid and offer prices are firm quotations.

Rule 15g-4—Broker-Dealer Compensation

Rule 15g-4 makes it unlawful for a broker-dealer to effect a penny stock transaction for a customer unless the broker-dealer discloses to the customer, both prior to effecting the transaction and at the time of confirming the transaction, the aggregate amount of any compensation received in connection with such transaction. "Compensation" is defined in the rule as: (1) in the case of an agency transaction, the amount of any remuneration received or to be received from a customer in connection with the transaction; (2) in the case of a "riskless principal" transaction, the difference between the price to the customer and the contemporaneous purchase or sale price to the broker-dealer; and (3) otherwise in the case of a principal transaction, the difference between the price to the customer and the prevailing market price in the security. This release contains a discussion of the criteria to be used for determining "prevailing market price."

In addition, Rule 15g-4 provides an alternative method of calculating compensation in principal transactions, permitting market makers to use an "active and competitive market" standard in calculating prevailing market price solely for purposes of Rule 15g-4, provided that the aggregate volume of transactions effected by the market maker in the penny stock in the five business days preceding such transaction is less than 20% of the aggregate amount of all transactions in the penny stock reported on a Qualifying Electronic Quotation System. However, this option would not be

[3] *i.e.*, total revenue of at least $18 million by the end of three years.

available to market makers until last sale reporting is included on such a quotation system.

Rule 15g–5—Associated Person Compensation

Rule 15g–5 makes it unlawful for a broker-dealer to effect a transaction in any penny stock for a customer unless the broker-dealer first discloses and subsequently confirms to the customer specified information with respect to any associated person, other than a person whose functions are solely clerical or ministerial, that has communicated with the customer concerning the transaction at or prior to the receipt by the broker-dealer of the customer's order. This information includes the aggregate amount of cash compensation that the associated person of the broker-dealer has received or will receive from any source in connection with the transaction and that is determined at or prior to the transaction, as well as separate disclosure of the source and amount of any compensation that is paid by persons other than the broker-dealer. In addition, if the associated person may receive contingent compensation that is not disclosed prior to the transaction because the amount of such compensation is not determined at or prior to the transaction, the written confirmation disclosure must describe the basis upon which such additional compensation is calculated.

Rule 15g–6—Monthly Account Statements

Rule 15g–6 requires a broker-dealer that has sold penny stocks to a customer in transactions that are not exempted by Rule 15g–1 to provide to that customer monthly account statements concerning these securities. The status of a security as a penny stock for purposes of this rule is determined on the last trading day of the month. The statement must be sent within ten days following the end of the month to which it pertains.

Each statement must disclose the identity and number of shares of each penny stock held in the customer's account and the estimated market value of the security, based on the highest inside bid quotation displayed on a Qualifying Electronic Quotation System or recent purchases by the broker-dealer, if available. The statement also must contain a standardized legend that provides certain disclosures relating to the estimated market value shown on the statement.

Rule 15g–6 exempts a security from the monthly account statement requirement following a particular quarter, if the security consistently (during all but five trading days) trades at a price of at least five dollars per share during the quarter. In addition, if the broker-dealer has not effected any penny stock transactions for the customer for six consecutive months, the rule permits account statements to be provided on a quarterly basis.

II. Introduction

The Penny Stock Act and the Rules are part of a comprehensive effort by the Congress and the Commission to reduce fraud and manipulation in the penny stock market and to provide investors with important information concerning that market. Although speculation in penny stocks, often fueled by fraudulent sales practices, has long existed in the United States, advances in communications technology have contributed to substantial growth in these activities in recent years. False representations and manipulative trading patterns, often by repeat offenders, have been facilitated by the absence of a visible market and a lack of investor information and education.[4]

In response to these developments, the Commission, along with other federal departments and agencies, the NASD, and state authorities have increased enforcement activities, promoted investor education, and adopted regulatory changes.[5] To date, the primary regulatory response by the Commission has been the adoption of Rule 15c2–6,[6] which became effective on January 1, 1990.[7] In general, that rule requires that a broker-dealer effecting transactions for customers in designated securities make a documented determination that the transactions are suitable for those customers and obtain the customers' written agreement to the transactions.

The Penny Stock Act contains provisions designed to target abuses in the penny stock market in a variety of ways, including, among others, the expansion of the Commission's enforcement authority with respect to persons associated with penny stock offerings, promoting the development of automated quotation systems for penny stocks, restrictions on "blank check" offerings, and broker-dealer disclosure requirements.[8] The disclosure provisions are contained in section 15(g) of the Exchange Act, which requires the Commission to adopt rules: (i) Governing the content and form of a risk disclosure document required to be provided by broker-dealers to their customers prior to effecting transactions in penny stocks with those customers; (ii) requiring broker-dealers to disclose, prior to each penny stock transaction and on the customer's confirmation, information concerning bid and ask prices and compensation to be paid to the broker-dealers and their associated persons; and (iii) requiring broker-dealers to provide to customers monthly statements showing the market value of penny stocks held in customer accounts. Section 15(g)(4) provides the Commission with authority to exempt classes of persons or transactions from these disclosure requirements or to adopt additional regulations not mandated by statute.

Pursuant to the Penny Stock Act, in the Proposing Release, the Commission proposed rules defining the term penny stock, covering each of the disclosure areas described above, and providing certain exemptions. In addition, the Commission proposed requiring disclosure of a broker-dealer's role as a sole market maker in a penny stock when effecting transactions in the security for customers.

The Commission solicited comment in the Proposing Release relating to a variety of matters, including the effectiveness of the proposed rules in deterring fraud in the penny stock market, the value of the information required to be furnished to investors, and the costs and operational difficulties that would be faced by broker-dealers subject to the rules. In addition, the Commission was particularly concerned with the potential effect of the proposed rules on the ability of legitimate small issuers to obtain capital needed for growth.

The Commission received 73 written comments relating to the proposed rules.[9] In addition, members of the Commission's staff spoke directly to various broker-dealers, lawyers, and other securities market participants with respect to compliance issues and the potential impact of the proposed rules on small business capital formation.[10]

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[4] *See* Proposing Release, 56 FR 19168–19169.

[5] *Id.* at 19169–70.

[6] 17 CFR 240.15c2–6.

[7] Securities Exchange Act Release No. 27160 (August 22, 1989), 54 FR 35468 ("Rule 15c2–6 Release").

[8] *See generally* House Comm. on Energy and Commerce, *Report to accompany the Penny Stock Reform Act of 1990*, H.R. Rep. No. 617, 101st Cong. 2d Sess. (July 23, 1990) (reporting H.R. 4497) (hereinafter, "House Report"). The Commission is also today adopting new rules, pursuant to the Penny Stock Act, applicable to blank check offerings.

[9] A detailed comment summary has been prepared by the staff and placed in the Commission's public files, together with all comment letters received. *See* File No. S7–8–91.

[10] Memoranda summarizing the staff's contacts with 15 broker-dealers are contained in File No. S7–8–91.

The overwhelming majority of comments voiced general support for the need to prevent fraud in the penny stock market and for the Commission's efforts in this regard. However, the comments were sharply divided over the scope of the proposed rules, in terms of the classes of securities and transactions that would be covered, the comprehensiveness of the information required to be disclosed, and the manner and frequency with which it would be provided. One group of comments, submitted primarily by state regulatory authorities and consumer groups, supported the proposed rules in this respect or suggested that proposed definitional exclusions or transactional exemptions, or other provisions, would unduly limit the effectiveness of the rules.[11]

A much larger group of comments claimed that the application of the proposed rules was too broad, or that they would pose unworkable compliance burdens on broker-dealer firms in one or more particular respects. The largest single objection raised by these comments was the inclusion of securities quoted on NASDAQ, other than NMS securities, within the penny stock definition. Many of these and other comments suggested that the proposed rules would significantly limit the ability of companies covered by the rules to raise capital in the securities markets and would negatively affect the existing market for the stock of these issuers, because of the compliance burdens caused by the rules, the unwillingness of broker-dealer firms to effect transactions in these securities, or the negative connotation of being classified as a penny stock.

The Rules adopted by the Commission today reflect its concern that the Rules not stifle the formation of capital for legitimate small companies or eliminate a viable secondary market for their securities. The Commission recognizes the important economic function served by small companies and recently has proposed to ease certain filing requirements and limitations applicable to limited offerings by small issuers and increase the percentage of investment company assets that may consist of illiquid assets, such as the securities of small issuers.[12]

Many of the new provisions incorporated in the Rules are intended to maintain the access of small ventures to capital markets where this may be accomplished consistent with the Commission's primary charter to protect investors. In considering this issue, the Commission also recognizes that fraudulent sales practices, which have occurred disproportionately in this market, may themselves hinder economic growth, because they cause the loss of the productive use of investor funds and discourage further investment by those who have been defrauded.[13] Legitimate small business is thus harmed by the diversion of substantial capital to unscrupulous promoters and broker-dealers. Moreover, issuers of penny stocks that are fraudulently traded may themselves be victimized by this activity.[14]

The Commission has also considered, in reviewing the Rules, certain recent developments, including increases in listing and maintenance standards applicable to NASDAQ securities[15] and the NASD's proposal, which has been approved,[16] to apply to non-NMS NASDAQ securities transaction reporting requirements similar to those already applicable to NMS securities.[17] The Commission believes that these developments significantly lessen the potential that NASDAQ securities will be subject to fraudulent sales practices.[18] In addition, the Commission has noted the experience of the NASD in operating its OTC Bulletin Board, which provides automated quotations by market makers in penny stocks ("Bulletin Board").[19] The Commission believes that the Bulletin Board may presage the evolution of a more transparent and reliable market for the shares of promising small companies that are not quoted on NASDAQ or traded on a national securities exchange.

After considering these factors and the comments it has received, the Commission is adopting the Rules with modifications to certain provisions contained in the proposed rules. These changes are intended to limit potential negative effects of the Rules on small business capital formation by (i) modifying the definitional and exemptive provisions in order to limit the application of the Rules to those securities and transactions involving the greatest potential for abuse and (ii) streamlining certain operational aspects of the Rules in order to simplify compliance responsibilities for broker-dealer firms. Among the changes reflected in the Rules are the following: (i) The effective exclusion from the application of the Rules of non-NMS NASDAQ securities at the point in time when last sale reporting requirements are in place for such securities; (ii) an exclusion from the penny stock definition for securities of issuers with specified net tangible assets or revenues; (iii) an exemption for private placement and Regulation D offerings; (iv) expanded availability of the exemption for broker-dealers doing a *de minimis* business in penny stocks; (v) various changes to individual Rules designed to ameliorate compliance burdens, including the use of quotations on the NASD's Bulletin Board, where available, to satisfy various pricing provisions of the Rules; and (vi) deferral of action on proposed Rule 15g-7, requiring disclosure of a firm's status as a sole market maker, which was not mandated by the Penny Stock Act. The Commission believes that these changes will implement the Congressional directive contained in the Penny Stock Act while maintaining the ability of viable small companies to obtain equity capital.

III. The Rules

A. Rule 3a51-1: Definition of Penny Stock

New section 3(a)(51)(A) of the Exchange Act defines the term "penny stock" as any equity security[20] other

[11] A comment supporting the proposed rules and opposing less stringent requirements also was submitted by the Hon. Edward J. Markey, Chairman of the Subcommittee on Telecommunications and Finance of the U.S. House of Representatives.

[12] Securities Act Release No. 6924 (March 11, 1992), 57 FR 9768; Securities Act Release No. 6926 (March 12, 1992), 57 FR 9825; Investment Company Act Release No. 18612 (March 12, 1992), 57 FR 9828.

[13] *See* House Report 10-12; Proposing Release, n. 9. In a recent penny stock fraud case, a federal court expressed the point in these terms: "Defendants' contemptible conduct did more than harm their clients; their actions destroy investor confidence, pollute the environment for securities transactions, and bring disgrace and shame upon Wall Street." *SEC v. Hasho*, [Current] Fed. Sec. L. Rep. (CCH) ¶ 96,502, at 92,237, 92,239 (S.D.N.Y. 1992).

[14] Proposing Release, 56 FR 19169.

[15] Securities Exchange Act Release No. 29638 (August 30, 1991), 56 FR 44108.

[16] Securities Exchange Release No. 30569 (April 10, 1992).

[17] Securities Exchange Act Release No. 30392, (February 21, 1992), 57 FR 6880.

[18] *See* discussion at section III.A.2.a, *infra*.

[19] *See* discussion at section III.A.3.b below.

[20] The term "equity security" is defined in section 3(a)(11) of the Exchange Act (15 U.S.C. 78c(a)(11)) as:

Any stock or similar security; or any security convertible, with or without consideration, into such a security, or carrying any warrant or right to subscribe to or purchase such a security; or any such warrant or right; or any other security which the Commission shall deem to be of similar nature and consider necessary or appropriate, by such rules and regulations as it may prescribe in the public interest or for the protection of investors, to treat as an equity security.

Rule 3a11-1 (17 CFR 240.3a11-1) further defines "equity security" to include:

Any stock or similar security, certificate of interest or participation in any profit sharing agreement, preorganization certificate or

Continued

than a security that is: (1) Registered, or approved for registration, and traded on a national securities exchange that meets criteria prescribed by the Commission; (2) authorized for quotation on an automated quotation system sponsored by a registered securities association, if such system was established and in operation before January 1, 1990, and meets criteria prescribed by the Commission; (3) issued by an investment company registered under the Investment Company Act of 1940; or (4) excluded or exempted, on the basis of exceeding a minimum price, net tangible assets of the issuer, or other relevant criteria, from the definition of the term "penny stock" by rule or regulation prescribed by the Commission. Section 3(a)(51)(A) determines the extent of the Commission's authority under section 15(b)(6)(A) of the Exchange Act to censure, suspend, bar, or restrict the activities of persons participating in an offering of penny stock. This section also defines the Commission's authority to adopt rules under section 15(g) of the Exchange Act imposing additional broker-dealer disclosure requirements or other obligations with respect to penny stocks and to prescribe rules under section 7(b) of the Securities Act governing registration statements of blank check companies. [21]

The Commission is adopting Rule 3a51–1 to implement the provisions of section 3(a)(51) of the Act. Rule 3a51–1 excludes from the definition of penny stock any equity security that is: (1) A "reported" security; (2) a put or call option issued by the OCC; (3) priced at five dollars or more, as determined (a) on a per transaction basis, or (b) on the basis of the inside bid quotation displayed on a Qualifying Electronic Quotation System, or if there is no such inside bid quotation, the average of at least three interdealer bid quotations displayed in an interdealer quotation system; (4) subject to last sale reporting and (a) registered, or approved for registration upon notice of issuance, on a national securities exchange and purchased or sold in a transaction executed on the exchange or in a distribution, or (b) authorized, or approved for authorization upon notice of issuance, for quotation on NASDAQ; or (5) whose issuer has (a) net tangible assets in excess of $2 million, if that issuer has been in continuous operation for at least three years, or $5 million, if the issuer has been in continuous operation for less than three years, or (b) average revenue of at least $6 million for the last three years. The most significant change from the proposed rule is the exclusion, subject to certain limitations, of regional exchange-listed and NASDAQ securities from the definition of penny stock. [22] As discussed further below, the rule contains several other modifications from the proposed rule that are designed to address the suggestions made in the comments.

1. Reported Securities

As adopted, Rule 3a51–1 excludes from the definition of penny stock any equity security that is a reported security—that is, any exchange-listed or NASDAQ security for which transaction reports are required to be made on a real-time basis pursuant to an effective transaction reporting plan. [23] The proposed rule also contained an exclusion for reported securities. In the Proposing Release, the Commission concluded that reported securities should be excluded from the penny stock rules because they are subject to rules of the self-regulatory organizations ("SROs") that set specific standards for inclusion, promote efficient pricing and transaction execution procedures, and generate public price information for evaluation by professional securities analysts and the financial press. [24]

The comments generally agreed with this conclusion, [25] and so Rule 3a51–1 continues to exclude reported securities from the definition of penny stock. Thus, securities listed on the NYSE, certain regional exchange-listed securities that meet NYSE or Amex original listing criteria, as well as NASDAQ NMS securities, are not considered penny stocks under paragraph (a) of the rule. [26]

As reported securities, securities that are listed on Amex pursuant to Amex's original and junior tier, or ECM, listing criteria [27] also are not considered penny stocks for purposes of the Rules. Securities listed on Amex as part of the ECM, however, continue to be deemed "penny stocks" solely for purposes of section 15(b)(6) of the Exchange Act. Although ECM securities are subject to real-time reporting requirements, they are not required to meet the same stringent listing and maintenance criteria as required for securities listed on Amex under the exchange's regular standards. In fact, the requirements for listing on the ECM are comparable to the current eligibility requirements for NASDAQ (non-NMS) securities. As discussed further below, securities that are quoted on NASDAQ are excluded from the definition of penny stock, except for purposes of Section 15(b)(6) of the Exchange Act.

The Commission believes that Amex's ECM securities should be treated in the same manner under the Rules as NASDAQ (non-NMS) securities. Excluding ECM securities from the definition of penny stock for all purposes would be unwarranted in view of the fact that the listing criteria for ECM and NASDAQ issuers are similar, and potentially could provide Amex's ECM with an unfair competitive advantage. The Commission therefore has determined to subject Amex's ECM securities to the same condition as is applicable to NASDAQ securities, discussed below, by including them in the definition of penny stock solely for purposes of Section 15(b)(6) of the Exchange Act.

2. Other NASDAQ and Exchange-Listed Securities

a. *Last sale reporting.* Although proposed Rule 3a51–1 excluded reported securities from the definition of penny stock, it did not exclude non-reported securities, such as securities that are quoted on NASDAQ but that are not designated as NMS securities. [28] The

subscription, transferable share, voting trust certificate or certificate of deposit for an equity security, limited partnership interest, interest in a joint venture, or certificate of interest in a business trust; or any security convertible, with or without consideration into such a security, or carrying any warrent or right to subscribe to or purchase such a security; or any such warrant or right; or any put, call, straddle, or other option or privilege of buying such a security from or selling such a security to another without being bound to do so.

[21] *See* 15 U.S.C. 77g(b)(3) (defining "blank check company" as any development stage company that is issuing a penny stock, as defined in section 3(a)(51) of the Exchange Act, and that either has no specific business purpose or has indicated that its business plan is to merge with an unidentified company).

[22] Under the proposed rules, these securities were not excluded from the definition of penny stock, but instead were exempted from certain disclosure requirements pursuant to Rule 15g–1. Rule 15g–1, as adopted, is discussed in section III.B of this release.

[23] See the definition of "reported security" in 17 CFR 240.11Aa3–1(a)(4).

[24] See 56 FR 19172–19173.

[25] In Amex's view, "[b]y utilizing last sale reporting, a marketplace can generate the type of detailed surveillance runs which are best able to deter would-be wrongdoers or lead to their ready detection and ultimate prosecution."

[26] In general, as reported securities, securities admitted to unlisted trading privileges on an exchange also are excluded under this provision.

[27] The Commission recently approved Amex's proposal to create a new "Emerging Company Marketplace," or ECM, to enable certain companies traded in the over-the-counter ("OTC") market that are too small to meet Amex's regular listing criteria to register their securities on the exchange. Securities Exchange Act Release No. 30445 (March 5, 1992), 57 FR 8693.

[28] In lieu of excluding these securities from the definition, under Rule 15g–1, the Commission

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Commission reasoned that persons investing in these securities could benefit from the disclosure provided by the penny stock rules because, unlike reported securities, these securities are not traded in a market that is subject to a comprehensive regulatory scheme requiring real-time transaction reporting, nor are they required to meet the same minimum qualification and maintenance criteria.[29] The Commission requested comment on whether the definition of penny stock nevertheless should be narrowed in order to avoid unnecessarily inhibiting small business capital formation.

As discussed above, the majority of the comments on the proposed rules objected to the inclusion of securities quoted on NASDAQ in the definition of penny stock.[30] These comments argued that the rules of the NASD, particularly the increased listing and maintenance standards for issuers of NASDAQ securities and the requirement that market makers in NASDAQ securities display firm bid and ask quotations, provide an adequate substitute for the protections afforded by the penny stock rules. Many of these comments also stated that there was insufficient evidence of fraud in the NASDAQ market to include NASDAQ securities in the scope of the Rules; in any case, they believed that the NASD's surveillance capabilities were sufficient to address any existing fraud in that market.

The Commission approved a NASD proposal to increase the listing and maintenance standards for NASDAQ securities in August of 1991.[31] These new standards ensure that securities that are quoted on NASDAQ represent companies that have generated significant shareholder interest and that have a demonstrated financial history and minimum pricing levels. In addition, the Commission today approved the NASD's proposal to amend Schedule D to the NASD By-laws to implement last sale price and volume reporting requirements for NASDAQ securities.[32] Under this rule proposal, NASD members will be required to report to the NASD the execution price and the number of shares of each trade within 90 seconds after execution. This information will then be validated by the NASD and be made available to information vendors for dissemination to the investment community and the public. In the NASD's view, the "resulting dissemination of real-time trade and volume data during market hours will significantly benefit investors by providing the same high degree of market visibility and more efficient price discovery for all * * * NASDAQ issues that currently exists for NMS and major exchange listed securities." Moreover, rather than relying on end-of-the-day statistics as the primary source of surveillance information for trades in NASDAQ securities, the NASD will have access to trading data through its equity audit trail, which currently integrates last sale, clearing, and inside quotation data for reported securities. The NASD's ability to detect and deter manipulative or abusive trading practices in the NASDAQ market thereby will be significantly enhanced.

The NASD also has filed a rule proposal to require all NASDAQ market makers to display minimum quotation sizes of five hundred shares.[33] If approved by the Commission, this rule change will provide investors with further information about the liquidity and depth of the market for NASDAQ securities. As the NASD stated in its comment letter, all of these rule changes will increase the transparency and liquidity of the market for NASDAQ securities, thus reducing the need for the additional disclosure provided by the penny stock rules.

In light of these comments and the NASD's rule changes, the Commission has amended Rule 3a51–1 to exclude from the definition of penny stock any security that is authorized, or approved for authorization upon notice of issuance,[34] for quotation on NASDAQ, provided that price and volume information with respect to transactions in that security is required to be reported on a current and continuing basis and is made available to vendors of market information pursuant to the rules of the NASD.[35] In the Proposing Release, the Commission emphasized that many of the abuses occurring in the penny stock market are a direct result of the lack of publicly available information about the market in general and about the price and trading volume of particular penny stocks. The Commission believes that the NASD's proposal to implement last sale reporting for NASDAQ securities will increase the transparency of the market for NASDAQ securities. This rule change, combined with the NASD's increased listing criteria for NASDAQ issuers and its surveillance of the NASDAQ market, will provide sufficient protection to investors to substitute for the disclosure provided by the penny stock rules. Therefore, when the NASD implements last sale reporting pursuant to the terms of its proposal, all NASDAQ securities will be excluded from the definition of penny stock under paragraph (f) of Rule 3a51–1.[36]

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proposed to exempt transactions in NASDAQ and exchange-listed securities from the requirements of Rules 15g–2, 15g–3, and 15g–6.

[29] *See* Proposing Release, 56 FR 19173, n. 58, and accompanying text.

[30] *E.g.*, NASD. A small number of comments, primarily submitted by state regulatory authorities and consumer groups, believed that the definition should cover all non-reported securities. See discussion, *infra*.

[31] Securities Exchange Act Release No. 29638 (August 30, 1991), 56 FR 44106. For instance, the initial listing requirements for issuers were increased from $2 million in total assets and $1 million in capital and surplus, to $4 million in total assets and $2 million in capital and surplus. The rule change also added a minimum initial price requirement of $3.00 per share and increased the number of market makers required for continued quotation in the system from one to two.

[32] Securities Exchange Act Release No. 30569 (April 10, 1992); and Securities Exchange Act Release No. 30392 (February 21, 1992), 57 FR 6880. Anticipating this rule change, six comments specifically suggested that, in lieu of applying the penny stock rules to non-reported securities, the Commission should address any perceived problems in the NASDAQ OTC market by extending real-time transaction reporting requirements to NASDAQ securities.

[33] Securities Exchange Act Release No. 29859 (October 25, 1991), 56 FR 56258.

[34] One comment suggested that securities underwritten on a best efforts basis should be considered "approved for authorization upon notice of issuance" on NASDAQ, even when NASD approval is contingent upon the amount of proceeds raised by the offering. Schedule D to the NASD's By-laws, however, provides that a new issue offered on a best efforts basis will be considered for inclusion under NASD rules only upon the closing of the offering if the issuer is relying on the proceeds of that offering to satisfy the NASDAQ financial authorization criteria. Accordingly, under Rule 3a51–1(f), securities underwritten on a best efforts or contingency basis will not be considered to be "approved for authorization upon notice of issuance" in the NASDAQ system if NASD approval is contingent in whole or in part upon the amount of proceeds raised by the offering.

In contrast, under the rules of the NASD, a new issue offered on a firm commitment basis will be considered for inclusion in the NASDAQ system when the registration statement is declared effective by the Commission or other appropriate regulatory authority. Therefore, if prior contingent approval has been received from the NASD, securities that are offered on a firm commitment basis will be considered to be "approved for authorization upon notice of issuance" in the NASDAQ system under Rule 3a51–1 at the time the registration statement becomes effective, provided that the NASDAQ financial authorization criteria are satisfied at that time. See NASD Schedules to the By-Laws, Schedule D, pt. II section 1, *NASD Manual* (CCH) ¶ 1803 (1990).

This position is consistent with the Commission staff's interpretation of the analogous provisions of Rule 15c2–6. See *Rechargeable Battery Corporation*, [1990–1991] Fed. Sec. L. Rep. (CCH) ¶ 79,638, at 77,893 (May 7, 1990).

[35] This provision, together with the provision excluding exchange-listed securities, discussed below, replaces the exclusion in proposed Rule 3a51–1 for securities that are registered and traded on a national securities exchange or quoted on an automated quotation system that has the authority to delist the securities of an issuer with less than $2 million in net tangible assets or stockholders' equity.

[36] As discussed above, NASDAQ NMS securities are excluded pursuant to paragraph (a) of the rule.

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For similar reasons, Rule 3a51–1 as adopted provides an exclusion in paragraph (e) for any security that is registered, or approved for registration upon notice of issuance, on a national securities exchange, [37] provided that current price and volume information with respect to transactions in that security is required to be reported and is made available to vendors pursuant to the rules of the national securities exchange.[38] Securities that are listed on the regional exchanges also are subject to general reporting requirements under the rules of those exchanges. Investors therefore have a greater ability to evaluate and to monitor the market price of listed securities without having to rely exclusively on the representations of their broker-dealer. In addition, issuers of these securities are required to meet minimum qualification and maintenance standards for listing on the exchange. The Commission believes that these requirements, together with comprehensive exchange surveillance, also make the protections provided by the penny stock rules less necessary for securities listed and traded on the regional exchanges.[39]

The exclusion in paragraph (e) of Rule 3a51–1 is limited to exchange-listed securities that actually are purchased or sold through the facilities of the exchange or in a distribution. This restriction is intended to address Congress' concern that securities that would otherwise be considered penny stocks because they are primarily traded in the non-NASDAQ OTC market nevertheless may be able to avoid the requirements of the Rules by becoming listed on an exchange.[40] By limiting the exclusion in paragraph (e) to specific transactions, the rule ensures that the information required under the Rules will be provided to customers in transactions executed by dealers as principal away from the exchange market, where the dealers' quotations generally are not made public and electronic surveillance is less effective.[41]

b. *Section 15(b)(6).* Paragraphs (e) and (f) of Rule 3a51–1 generally remove exchange-listed and NASDAQ securities from the definition of penny stock for purposes of section 15(g) of the Exchange Act and section 7(b) of the Securities Act and the rules promulgated thereunder. These securities nevertheless continue to be deemed penny stocks for purposes of section 15(b)(6) of the Exchange Act.[42]

Section 15(b)(6) gives the Commission the authority to prohibit any person that has engaged in unlawful conduct while participating in a distribution of penny stock, as defined in Rule 3a51–1, from associating with a broker-dealer or participating in a distribution of penny stock, if the Commission finds that such a restriction would be in the public interest. Under this section, broker-dealers also are prohibited from allowing such persons to participate in a distribution of penny stock without the Commission's consent. According to the House Report, subparagraph (6)(A) was added to section 15(b) to enable the Commission to prohibit persons from participating in penny stock activities through remote affiliations with issuers and broker-dealers and to give the Commission broader prescriptive authority to address patterns of recidivism in the penny stock market.[43]

In the Proposing Release, the Commission solicited comment on whether the exclusions from the definition of penny stock would provide particular opportunities for persons with a disciplinary history to become involved, as promoters or other associated persons of an issuer or broker-dealer, in offerings of penny stock. In response, several state securities regulators, NASAA, and the Consumer Federation of America ("CFA") argued that regional exchange-listed and NASDAQ securities should be included in the definition of penny stock in part to prevent persons with an established record of fraudulent activity in the low-priced securities market from associating with issuers of those securities and their broker-dealers.[44]

Although the Commission recognizes that last sale reporting and SRO supervision will address many of the problems that the penny stock disclosure rules are designed to remedy, the Commission believes that the markets for low-priced securities listed or quoted on the regional exchanges, Amex's ECM, and NASDAQ would be strengthened by protecting them from

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Securities that are quoted on the NASD's Bulletin Board, however, are not excluded from the definition of penny stock.

[37] This exclusion is conditioned on the national securities exchange making transaction reports available for at least some securities pursuant to Rule 11Aa3–1. Exchanges that currently qualify for this exclusion are the NYSE, Amex, the Boston Stock Exchange, the Cincinnati Stock Exchange, the Midwest Stock Exchange, the Pacific Stock Exchange, the Philadelphia Stock Exchange, and the Chicago Board Options Exchange, which was authorized to provide transaction reports for equity securities other than options in Securities Exchange Act Release No. 28808 (January 22, 1991), 56 FR 3124. *Cf.* n. 34, *supra.*

[38] These exchange-listed securities do not need to be reported pursuant to the Restated Consolidated Tape Association Plan to satisfy the requirements of this provision.

[39] In addition, because put and call options issued by the OCC are already subject to special disclosure requirements, they are separately excluded from the definition of penny stock in paragraph (c) of Rule 3a51–1. See, *e.g.*, 17 CFR 240.9b–1; CBOE Rules, Rules 9.1–9.23, *CBOE Guide* (CCH) ¶¶ 2301–23; and NASD Rules of Fair Practice, appendix E, *NASD Manual* (CCH) ¶ 2184.

Trans Canada Options Inc. ("TCO") argued that, like OCC options, Canadian put and call options issued by TCO should be excluded from the coverage of Rule 3a51–1. According to TCO, these securities generally have not been the subject of fraudulent activities because they are traded in markets that are subject to comprehensive regulation, and because they are subject to the same risk disclosure scheme as options issued by the OCC. The Commission believes that most foreign securities, such as options issued by TCO, that are traded in markets other than NASDAQ or a national securities exchange will be exempt from the coverage of the Rules based on the five dollar price or the net tangible assets/revenue exclusion in Rule 3a51–1. The Commission, however, has specifically retained exemptive authority under paragraph (f) of Rule 15g–1 for foreign securities that do not qualify for these exemptions but that are otherwise subject to alternative, comprehensive disclosure schemes. See discussion, *infra.*

[40] The House Report stated that:

[t]he Committee is aware that certain securities that should properly be categorized as penny stocks may be able to gain registration on regional exchanges. Once registered on an exchange, most of the trading activity in these securities may be directed to the non-NASDAQ over-the-counter market, where a lack of trading or quotation information, higher spreads and markups, and other factors may operate to the disadvantage of public investors. Similarly, the fact that a security is authorized for quotation on NASDAQ would not preclude a market maker in the security from effecting transactions in the security without entering quotations in NASDAQ. Therefore, if exchange registration or NASDAQ authorization provided a complete exemption from the penny stock definition, investors effecting transactions in these securities with dealers in the non-NASDAQ over-the-counter market could be disadvantaged.

House Report at 27.

[41] Similarly, the exclusion in paragraph (f) for NASDAQ securities is conditioned on the NASD implementing last sale reporting for NASDAQ securities. As discussed above, under the NASD's last sale reporting proposal, transactions in NASDAQ securities generally will be required to be reported to the NASD on a real-time basis, regardless of the market in which they are effected.

[42] In addition, although securities listed on Amex pursuant to Amex's junior tier, or ECM, listing criteria are not considered penny stocks for purposes of the Rules and section 7(b) of the Securities Act, they are deemed penny stocks solely for purposes of section 15(b)(6) of the Exchange Act. See discussion of Rule 3a51–1(a), *supra.*

[43] House Report at 28.

[44] The Securities Division of the State of Delaware, for instance, commented that the definition of penny stock should be broad because "[s]elling securities at greatly inflated prices is such a lucrative operation that the individuals behind these firms are not likely to abandon their unscrupulous practices merely because of regulatory efforts aimed at the non-NASDAQ OTC market. Rather, it is more likely that they will seek to infiltrate the low end of the NASDAQ market and to continue to engage in market manipulation and excessive price mark-ups, albeit in a more selective and less transparent manner."

persons with a history of penny stock abuse.[45]

The Commission therefore has retained the authority under section 15(b)(6)(A) of the Exchange Act to restrict such persons from becoming involved in those markets by excluding regional exchange-listed, ECM, and NASDAQ securities only from the requirements of section 15(g) of the Exchange Act and section 7(b) of the Securities Act. Specifically, paragraphs (e)(2) and (f) of Rule 3a51–1 provide that exchange-listed and NASDAQ securities that are not otherwise excluded from the definition of penny stock are considered to be penny stocks solely for purposes of section 15(b)(6) of the Exchange Act. As discussed above, under paragraph (a) of Rule 3a51–1, securities that are registered on Amex pursuant to its ECM listing criteria also are included in the definition of penny stock for purposes of section 15(b)(6).

3. Price of the Security

a. *Transactions.* As adopted, Rule 3a51–1(d) excludes from the definition of penny stock securities that are priced at five dollars or more. In most cases, the price of a security for purposes of the rule will be the price at which it is purchased or sold in a particular transaction, excluding the amount of any broker-dealer commission, commission equivalent, mark-up, or mark-down.

The proposed rule contained a similar exclusion for securities priced at five dollars. The comments were sharply divided on whether the five dollar price threshold was appropriate. Several comments supported the five dollar price threshold on the ground that lower-priced securities are more susceptible to manipulation. In contrast, other comments argued that the five dollar price was arbitrary, and suggested alternative prices, ranging from one cent to three dollars, which they believed would more accurately reflect the common understanding of the term "penny stock." The Regional Investment Brokers, Inc. recommended that the price threshold be entirely eliminated because, by itself, it does not provide an accurate indication of the quality of a company.[46]

The Commission has determined to retain a five dollar price threshold in Rule 3a51–1 for several reasons. First, as noted in the Proposing Release, securities priced above five dollars are less frequently the vehicle for manipulation and high pressure sales campaigns because the percentage price spreads at that level are much lower. In contrast, securities selling for under five dollars are often used in manipulative schemes due to the potential for immediate profits from large percentage spreads.[47] A broker-dealer, for instance, can sell a large volume of securities priced below three dollars by representing to unwary customers that small absolute price increases constitute large returns in relation to the purchase price.[48] The higher the price of the security, however, the harder it is for a broker-dealer to maintain large percentage spreads or to tout a security based on small price increases; that is, it becomes more difficult to sell a large volume of securities solely for the purpose of generating rapid profits.[49] Thus, the Commission has included a five dollar price threshold in the rule because it believes that manipulation and sales practice abuses are less likely to occur at that level. The five dollar threshold, however, is not intended to provide any indication of the inherent worth of a company.[50]

Second, the five dollar price threshold is consistent with the Uniform Limited Offering Registration ("ULOR") project developed by the State Regulation of Securities Committee of the American Bar Association and NASAA to provide a short-form registration procedure for small business offerings priced above five dollars.[51] The price threshold also is consistent with a number of other existing price standards.[52]

Finally, the minimum price threshold serves an important function by mitigating the impact of the penny stock rules on legitimate small business capital formation. The Commission's experience with a similar threshold in Rule 15c2–6, confirmed by discussions with a number of broker-dealers, indicates that the price threshold will allow small issuers to respond to the Rules by setting the initial offering price for their securities at five dollars or more, or by engaging in reverse stock splits to raise the price of their existing shares. Although a higher price structure reduces the number of shares of smaller issuers available for trading in the secondary market, it appears that, at a five dollar price level, this reduction does not substantially impede the liquidity of the market for those securities. Moreover, as discussed further below, the list of exempt transactions under Rule 15g–1 has been expanded to provide relief for legitimate small issuers attempting to raise capital. Accordingly, many small issuers will be able to avoid the requirements of the Penny Stock Act by relying on a transactional exemption from the disclosure rules.[53]

For the foregoing reasons, subparagraph (d)(1)(i) of the adopted rule excludes securities that are purchased or sold in a transaction at a price of five dollars or more. In order to prevent broker-dealers from charging excessive mark-ups to inflate the price of a penny stock above five dollars, the rule has been amended to provide that, in both agency and principal transactions, the price of a security is the price exclusive of the broker-dealer's remuneration.[54]

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[45] See, *e.g.*, *SEC* v. *Hasho*, [Current] Fed. Sec. L. Rep. (CCH) ¶ 96,502 (S.D.N.Y. 1992) (abusive sales practices involving NASDAQ securities); and cases cited in the Proposing Release at 56 FR 19173, n. 64.

[46] In this connection, a few comments expressed concern that the Rules will apply to all issuers whose securities are priced below five dollars, even issuers that have substantial assets. The Commission notes that the securities of issuers with substantial assets will be excluded from the Rules by virtue of paragraph (g), discussed below.

[47] Proposing Release, 56 FR 19174. In fact, in a dominated and controlled market, the per share profit to the broker-dealer may be much higher than the spread. See Rule 15c2–6 Release, 54 FR at 35469, n.14.

[48] The broker-dealer, however, typically will not explain that a large spread will undermine the investor's ability to later resell the security at a profit. See Rule 15c2–6 Release, 54 FR 35470.

[49] See Rule 15c2–6 Release, 54 FR 35469, 35475; and House Report at 12.

[50] See, generally, Proposing Release, 56 FR 19174.

[51] Specifically, ULOR (also known as Small Company Offering Registration, or SCOR) provides a streamlined state registration procedure for small businesses raising less than $1 million in offerings that are exempt from registration under Rule 504 of Regulation D [17 CFR 230.504]. In order to prevent abuses in the secondary market in securities issued pursuant to ULOR, as a general rule, issuers may only apply for ULOR registration if the offering price of their common stock, or the exercise or conversion price of any warrants, options, rights, or convertible securities included in the offering, is at least five dollars. See Rule 15c2–6 Release, 54 FR 35475; NASAA Reports (CCH) ¶ 5057, at 5198 (instructions to SCOR form); and Emshwiller, SCOR Funding Provides Short Form for Going Public, Wall St. J., Jan. 21, 1992, at B.2. See also Securities Act Release No. 6924 (March 11, 1992), 57 FR 9768.

[52] See, *e.g.*, 17 CFR 240.15c2–6; 12 CFR 220.17(a)(2) (five dollars per share requirement for inclusion on the list of OTC margin stocks); NASD Schedules to the By-Laws, Schedule D, pt. III, section 2, NASD Manual (CCH) ¶ 1809 (five dollars per share requirement for designation as a NMS security); Washington Administrative Code section 460–17A–030(2)(d), Blue Sky Law Reporter (CCH) ¶ 61,585C (five dollars per share requirement for offerings pursuant to ULOR); and Securities Exchange Act Release No. 30354 (February 18, 1992), 57 FR 5920 (five dollar offering price requirement for registration of "U–7," or ULOR, securities on the Pacific Stock Exchange, Inc.).

[53] In addition, some small issuers may be able to rely on the exclusion for reported securities under paragraph (a) of Rule 3a51–1, or the new exclusion under paragraph (g) for securities issued by issuers that meet certain financial criteria. See the discussion of Amex's ECM, *supra*.

[54] The proposed rule would have differentiated between agency and principal transactions in

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b. *Bid quotations.* As indicated above, the price of a security typically will be determined by the price at which it is purchased or sold in a particular transaction. In the absence of a transaction,[55] however, Rule 3a51-1(d)(1)(ii) provides that the five dollar price may be based on the inside bid quotation for the security displayed on a Qualifying Electronic Quotation System (*i.e.*, an automated interdealer quotation system that has the characteristics set forth in section 17B(b)(2) of the Exchange Act or any other system that is designated by the Commission for purposes of the rule).[56] The term "inside bid quotation" is defined in the rule as the highest bid quotation for the security displayed by a market maker in the security on such Qualifying Electronic Quotation System, provided that at the same time there are at least two market makers contemporaneously displaying in such system bid and offer quotations for the security.

Where there is no such inside bid quotation, subparagraph (d)(1)(ii) of Rule 3a51-1 provides that the average of at least three interdealer bid quotations at specified prices displayed in an interdealer quotation system [57] by three or more market makers in the security must be five dollars or more. The rule requires that the price be based on at least three bid quotations because quotations for low-priced securities that are traded in the non-NASDAQ OTC market, such as the pink sheets, frequently are the subject of negotiation and may not accurately reflect the prevailing market price.

The rule does not require a broker-dealer to conduct an independent investigation into whether the inside bid quotation or the three bid quotations upon which it is relying for purposes of the rule are *bona fide*. A broker-dealer, however, may not rely on quotations if it knows, or if it has reason to know, that those quotations have been entered into the interdealer quotation system by broker-dealers for the purpose of circumventing the requirements of the rule.[58]

As proposed, Rule 3a51-1 did not include a provision allowing broker-dealers to calculate the five dollar price based on the inside bid quotation displayed on a Qualifying Electronic Quotation System. This provision was added in response to the NASD's comment that the average price provision would be difficult for broker-dealers to comply with and for the Commission and the SROs to enforce. The Commission believes that permitting broker-dealers to determine the price of a security based on the inside bid quotation displayed on an automated quotation system that has the characteristics set forth in section 17B(b)(2) of the Exchange Act will facilitate compliance with the rule because, as discussed below, such information is readily available to broker-dealers.

Currently, no automated quotation system satisfies all of the requirements of section 17B(b)(2).[59] The Commission anticipates, however, that the Bulletin Board operated by the NASD may substantially meet those requirements by the effective date of the penny stock disclosure rules.[60] The NASD has made several enhancements to the Bulletin Board since it was first approved in May of 1990.[61] Specifically, NASD rules now require that quotations for domestic securities entered into the system by registered market makers must be firm for one unit of trading.[62] The NASD also calculates and distributes an inside quotation for each domestic security quoted in the Bulletin Board for which there are at least two registered market makers displaying firm two-sided quotations. Other changes have been made to the Bulletin Board to make the system more responsive to the operational needs of NASD member firms.[63] All of these changes are consistent with section 17B of the Exchange Act and, assuming that the Bulletin Board meets the requirements of section 17B(b)(2) by the effective date of the penny stock disclosure rules,[64] will facilitate broker-dealer compliance with Rule 3a51-1(d)(1)(ii) by providing readily available quotations upon which to calculate the five dollar price.

Finally, the NASD and the Securities Traders Association suggested that Rule 3a51-1(d) should be modified to account for price fluctuations occurring as a result of temporary market or economic conditions. Rather than complicate the five dollar price calculation in the definitional provision of Rule 3a51-1(d)(1)(ii) by taking into account temporary price fluctuations, the Commission has amended Rule 15g-6 to exempt from the monthly account statement requirement securities that are consistently priced above five

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determining the five dollar price. Specifically, under the proposed rule, the price of a security in an agency transaction or a contemporaneous offsetting purchase and sale principal transaction was the price exclusive of any broker-dealer commission, commission equivalent, mark-up, or mark-down. The price in all other principal transactions, however, was the price inclusive of the broker-dealer's mark-up or mark-down. The rule has been amended in response to the suggestion in several comments that the price should be calculated by excluding the broker-dealer's remuneration in all transactions. The State of Florida, for example, stated that "[e]xperience tells us that lower tiered stocks can be inflated by compensation above the five dollar threshold without much difficulty."

The Commission does not believe that this will create compliance problems because, under Rule 15g-4 (which requires disclosure of mark-ups and mark-downs for transactions in penny stocks), firms must establish procedures to quantify mark-ups and mark-downs in trades that potentially are subject to the Rules. See discussion at section III.E, *infra*.

[55] For instance, promoters, consultants, or other associated persons of a broker-dealer or issuer that have been barred pursuant to section 15(b)(6) of the Exchange Act from participating in penny stock transactions may rely on subparagraph (d)(1)(ii) to determine whether a particular security would be deemed to be a penny stock for purposes of section 15(b)(6). See also discussion of Rule 15g-6, *infra*.

[56] Section 17B(b) of the Exchange Act [15 U.S.C. 78q-2(b)] directs the Commission to facilitate the wide-spread dissemination of reliable and accurate last sale and quotation information with respect to penny stocks, with a view toward establishing one or more automated quotation systems to collect and disseminate information regarding penny stocks. See discussion, *infra*.

[57] "Interdealer quotation system" is defined in 17 CFR 240.15c2-7(c)(1) as "any system of general circulation to brokers and dealers which regularly disseminates quotations of identified brokers or dealers but shall not include a quotation sheet prepared and distributed by a broker or dealer in the regular course of his business and containing only quotations of such broker or dealer." This definition includes the Bulletin Board and other published quotation media of general circulation, such as the National Daily Quotation Service (the "pink sheets").

[58] NASD rules specifically prohibit NASD members from publishing any notice quoting a bid or offer price for a security, unless the member believes that such quotation represents a *bona fide* bid or offer. NASD Rules of Fair Practice, Art. III, § 5, NASD Manual (CCH) ¶ 2155. For further discussion of *bona fide* and independent quotations, see section III.G, *infra*.

[59] Although the NASD's system for quotation of NASDAQ NMS securities meets the requirements of section 17B, it is not an "automated quotation system for penny stocks" because NASDAQ NMS securities are not "penny stocks" under Rule 3a51-1.

[60] As discussed in section II above, the Bulletin Board is an automated system operated by the NASD that collects and displays quotation information for non-NASDAQ securities.

[61] Securities Exchange Act Release No. 27975 (May 1, 1990), 55 FR 19124.

[62] Securities Exchange Act Release No. 29261 (May 31, 1991), 56 FR 29297.

[63] See Securities Exchange Act Release No. 29713 (September 30, 1991), 56 FR 49500.

[64] If the Bulletin Board does not meet the requirements of section 17B(b)(2) by that date, the Commission will consider designating it or another system as a Qualifying Electronic Quotation System for purposes of compliance with the Rules.

In determining whether a particular system should be designated as a Qualifying Electronic Quotation System, the Commission will consider whether the system: (i) Is operated by or under the auspices of a SRO, or subject to comparable Commission review and oversight; (ii) collects and disseminates quotation and volume information; (iii) has effective surveillance capabilities and procedures; and (iv) makes widely available, on an electronic basis, bid and offer quotations of participating broker-dealers (or comparably accurate and reliable pricing information), including firm bid or offer quotations for at least such minimum number of shares or dollar amounts as the Commission and the SRO may require.

dollars during any quarterly period.[65] Amending subparagraph (d)(1)(ii) of Rule 3a51-1 to account for price fluctuations could create investor confusion as to whether a security is a penny stock at a given point in time and would be difficult for broker-dealers, the Commission, and the SROs to monitor.

c. *Unit pricing.* Paragraph (d)(2) of Rule 3a51-1 further provides that, in the case of a unit composed of different securities, the price divided by the number of shares of the unit that are not warrants, options, rights, or similar securities, must be five dollars or more, as determined in accordance with paragraph (d)(1) of the rule, and the exercise price of any warrant, option, or right, as well as the conversion price of any convertible security, included in the unit must be five dollars or more.[66] Merrill Lynch, Pierce, Fenner & Smith Inc. and the Securities Industry Association ("SIA") suggested that this provision should be eliminated from the rule because it could create confusion, especially when one of the securities in a unit is a "blue chip" stock, or when a derivative security that is a penny stock is convertible into a non-penny stock. The Commission notes, however, that these securities usually would be excluded under paragraphs (e), (f), or (g) of Rule 3a51-1.[67] In addition, the Commission believes that a customer who is buying separately traded securities (such as warrants) in the non-NASDAQ OTC market that are priced below five dollars and issued by a company with less than $2 million in net tangible assets or $6 million in three-year average revenues would benefit from the disclosure provided by the Rules.

4. *Issuer financial standards.* Finally, a new paragraph (g) has been added to Rule 3a51-1, which excludes any security issued by an issuer that has (1) net tangible assets in excess of $2 million, if that issuer has been in continuous operation for at least three years, or $5 million, if the issuer has been in continuous operation for less than three years, or (2) average revenue of at least $6 million for the last three years. As proposed, Rule 15g-1 contained a similar transactional exemption based on issuer net tangible assets.[68] The Proposing Release particularly solicited comment on whether the higher $5 million net tangible assets standard should apply to all issuers, regardless of their number of years in business.

The comments were divided on whether a two-tier standard for issuer net tangible assets was appropriate. While several comments responded that a single $2 million standard would be sufficient, NASAA and the State of Virginia indicated that the standard should either be eliminated, or raised to $5 million for all issuers. Four comments stated that Rule 15g-1 should not include any transactional exemption based on net tangible assets because such a standard is vague and easy to circumvent. In particular, one commenter believed that a net tangible assets standard would be unfair to certain industries (or companies within an industry) because accounting measurements may be evaluated differently depending on whether the industry of the issuer is oriented towards manufacturing or services. Several other comments, on the other hand, argued that the transactional exemption based on issuer net tangible assets should be replaced with a similar exclusion from the definition of penny stock so that securities that are issued by companies with substantial assets will not be considered "penny stocks."

In response to these comments, the Commission has amended Rule 3a51-1 to add an exclusion for securities issued by an issuer with either $2 million or $5 million in net tangible assets, depending on whether the issuer has been in operation for three years or less. Including a definitional exclusion based on issuer net tangible assets, rather than a transactional exemption, will simplify the Rules and be more consistent with Rule 15c2-6.[69] In addition, to address the comment that the standard is vague, the term "net tangible assets" is defined in the rule as total assets minus intangible assets and total liabilities. For purposes of the rule, intangible assets include, among other assets, goodwill, patents, licenses, and trademarks.[70] The rule continues to impose a separate higher standard for start-up companies in order to prevent the types of abusive activities described in the Proposing Release that have occurred both prior to and since the adoption of Rule 15c2-6 in August of 1989.[71]

Rule 3a51-1, however, also includes a new alternative revenue standard. Specifically, paragraph (g)(2) of the rule excludes any transaction in a penny stock issued by an issuer that has average revenues of $6 million for the prior three years. In other words, to satisfy the requirements of this provision, an issuer must have had total revenues of $18 million or more by the end of the three-year period.[72] The Commission believes that providing an alternative exclusion based on issuer revenue will ensure that the rule does not discriminate among issuers by industry, and will provide another basis upon which the securities of small issuers may be excluded from the application of the penny stock rules. The three-year revenue standard was selected over other standards,[73] because

[65] Because Rule 15g-6 is the only penny stock disclosure rule that is not specifically linked to transactions, it is the only rule that uses the calculation in subparagraph (d)(1)(ii) of Rule 3a51-1. In other words, to ascertain whether a monthly account statement would be required for a particular stock based on its price, a broker-dealer would need to determine whether the security has a price of five dollars or more under subparagraph (d)(1)(ii). To determine whether that same security would be subject to the requirements of Rules 15g-2 through 15g-5, however, the broker-dealer would look at the price at which the security was purchased or sold in a transaction; *i.e.*, the broker-dealer would calculate the price of the security pursuant to subparagraph (d)(1)(i) of Rule 3a51-1.

For further discussion of the amendments to Rule 15g-6, *see* discussion at section III.C, *infra*.

[66] For example, a unit composed of five shares of common stock and five warrants would satisfy the requirements of this paragraph only if the unit price was twenty-five dollars or more, and the warrant exercise price was five dollars or more. Once the components of the unit begin trading separately on the secondary market, they must each be separately priced at five dollars or more. See Proposing Release, 56 FR 19174, n. 72, and the NASD's Special Notice to Members No. 90-18, part B, Questions #17 and 18 (March 19, 1990).

[67] In most cases, a warrant or an option on a non-penny stock would be excluded from the definition of penny stock pursuant to the exclusion for securities whose issuers have a minimum level of net tangible assets or average revenue. See discussion of Rule 3a51-1(g), *infra*.

[68] Specifically, proposed Rule 15g-1(b) included an exemption for transactions in penny stocks issued by an issuer that has been in continuous operation for three or more years and has net tangible assets of at least $2 million, or that has been in continuous operation for less than three years and has net tangible assets of $5 million.

[69] As discussed further below, this modification also will expand the *de minimis* revenue exemption under Rule 15g-1(a).

[70] Categories in the issuer's financial statements that may include intangible assets, such as "Other Assets," also must be subtracted unless the broker-dealer determines that they consist only of tangible assets. The definition of intangible assets is discussed in further detail in Accounting Principles Board Opinion No. 17 (August, 1970).

[71] See 56 FR 19176. In addition, a two-tier standard has been adopted in several other contexts involving issuer qualification standards. *See, e.g.*, NASD Schedules to the By-Laws, Schedule D, pt. III, section 2, NASD Manual (CCH), ¶ 1809; and Amex Rules, part 10, section 1003, *Amex Guide* (CCH), ¶ 10,377.

[72] The exclusion therefore only applies to operating companies with a demonstrated three-year history of revenues.

[73] For example, Paulson Investment Company, Inc. suggested that the net tangible assets standard should be replaced with a standard that would require issuers to have had $2 million in cash investment in equity securities in the past five years. The Commission has not adopted this suggestion because cash investments cannot be easily ascertained from an issuer's financial statements. A paid-in capital standard also was rejected because it can be changed merely by increasing the par value of the issuer's shares.

it not only provides an indication of the financial history of a small company, but also because it can be readily derived from an issuer's income statement.

The $6 million revenue level was chosen because the Commission believes that, as a general rule, companies historically subject to penny stock manipulations and sales practice abuses have not achieved this level of revenue.[74] Like the exclusion based on issuer net tangible assets, however, this exclusion is not designed to give investors an indication of the investment merits of an issuer. Rather, it is intended only to exclude companies whose financial condition makes them less likely to be vehicles for abusive market activities even though their securities are traded outside of a transparent market at prices below five dollars.

The rule further provides that, for domestic issuers, the required level of net tangible assets or revenues must be demonstrated by financial statements that are dated less than fifteen months prior to the date of the related transaction and that have been audited and reported on by an independent accountant in accordance with Regulation S–X.[75] For foreign private issuers, the rule requires that net tangible assets or revenues be reflected in financial statements that are dated less than fifteen months prior to the date of the related transaction, and that have been filed with or furnished to the Commission pursuant to Rule 12g3–2(b).[76] If the foreign private issuer has not been required to file or furnish financial statements during the previous fifteen months, however, the financial statements may be prepared and audited in compliance with generally accepted accounting principles of the country of incorporation and reported on by an accountant registered and in good standing in accordance with the regulations of that jurisdiction. To demonstrate compliance with the rule, broker-dealers are required to keep copies of the domestic or foreign issuer's financial statements for at least three years following the date of the related transaction, the first two of which must be in an easily accessible place.[77]

In all cases, the broker-dealer must review the financial statements and have a reasonable basis for believing that they were accurate as of their date and that the issuer's financial condition has not substantially weakened by the date of the related transaction. A few comments argued that this requirement would impose a higher standard of review on broker-dealers than is required for auditors who report on the issuer's financial statements. These comments suggested that the Commission should rephrase the language of the rule to require that broker-dealers have "no reason to believe the statements are not accurate."

The Commission has not adopted this suggestion because, as noted in the Proposing Release, the existing standard does not require the type of "due diligence" investigation typically required of an underwriter or an auditor.[78] Rather, the rule requires broker-dealers to obtain audited financial statements from a reliable source, such as the issuer or the Commission, and to review those statements to ascertain whether the amount of the issuer's net tangible assets or revenues are in compliance with the rule. Ordinarily, if the issuer's audited balance sheet shows net tangible assets equaling either $2 million or $5 million (depending on the number of years the issuer has been in operation), or if its audited income statement shows average revenues of at least $6 million for the past three years, the broker-dealer will be entitled to rely on those statements to establish an exclusion under the rule.[79] Therefore, in most cases, the broker-dealer need not inquire about or independently verify any of the information contained in the issuer's financial statements. Only if materially inconsistent or inaccurate information appears on the face of the financial statements, or if the broker-dealer becomes aware, in the course of its review, of material inconsistencies between the statements and information in the broker-dealer's possession, would the broker-dealer need to satisfy itself that the information contained in the financial statements is accurate and complete.[80] The way in which a broker-dealer may satisfy itself as to the accuracy of an issuer's financial statements under the rule will vary according to the circumstances.[81] The Commission emphasizes, however, that under no circumstances would the rule require the type of "due diligence" investigation typically conducted by an underwriter.

B. Rule 15g–1: Exempt Transactions

In the Proposing Release, the Commission recognized that the rules proposed pursuant to section 15(g) of the Exchange Act potentially could affect legitimate small business capital formation. The Commission therefore proposed Rule 15g–1, which exempted certain transactions from the disclosure requirements of Rules 15g–2 through 15g–6. As originally proposed, the rule was organized in two parts: paragraph (a) exempted certain transactions from Rules 15g–2 through 15g–6, while paragraph (b) exempted transactions in securities listed on a national securities exchange or quoted on NASDAQ from Rules 15g–2, 15g–3, and 15g–6. Because exchange-listed and NASDAQ securities are now excluded from the definition of penny stock under Rule 3a51–1, paragraph (b) has been deleted from the final rule. In addition, as discussed below, the list of transactions that are exempt from Rules 15g–2 through 15g–6

[74] *See, e.g., SEC* v. *Hasho*, [Current] Fed. Sec. L. Rep. (CCH) ¶ 96,502 (S.D.N.Y. 1992); *SEC* v. *Phoenix Aviation, Inc.*, Litigation Release No. 12483 (May 22, 1990); and *SEC* v. *San Marino Securities, Inc.*, Litigation Release No. 12660 (Oct. 9, 1990).

This standard is higher than the minimum income requirement for quotation on NASDAQ. Unlike the NASDAQ market, however, the non-NASDAQ OTC market lacks last sale reporting and the accompanying automated SRO surveillance systems. In view of the lower transparency of this market, the Commission believes that the protections of the Rules should apply to the securities of somewhat larger issuers than those satisfying the minimum requirements for quotation on NASDAQ.

[75] 17 CFR 210.2–02.

[76] 17 CFR 240.12g3–2(b). Securities Exchange Act Release No. 28889 (February 22, 1991), 56 FR 7424, provides a list of foreign issuers that have submitted the information required by Rule 12g3–2(b) to date.

[77] See 17 CFR 240.17a–4(b).

[78] 56 FR 19176. Moreover, Rule 15c2–6, which contains a similar standard, has not been interpreted to require such an extensive review. See Rule 15c2–6 Release, 54 FR 35475, n. 45.

[79] Once a broker-dealer has reviewed the issuer's most recent audited financial statements and determined that the issuer qualifies for this exemption, the issuer will continue to qualify until the earlier of the following: (i) Fifteen months after the date as of which those financial statements reflect the issuer's financial condition; (ii) when the issuer produces more recent audited financial statements; or (iii) when the broker-dealer ceases to have a reasonable basis for believing that the financial statements reflect the current financial condition of the issuer.

[80] Rule 15c2–11 (17 CFR 240.15c2–11), which governs the submission and publication of quotations by broker-dealers for non-NASDAQ OTC securities, contains a similar standard. For further discussion of what constitutes a "reasonable basis for believing" that information is accurate, see Securities Exchange Act Release No. 29094 (April 25, 1991), 56 FR 19148, adopting amendments to Rule 15c2–11. This release discusses the types of "red flags" that generally should call into question information that has been provided to a broker dealer.

[81] For example, the broker-dealer may deem it appropriate to directly consult with the issuer or its accountant. The broker-dealer, however, may not rely on information from any outside source, such as the issuer, to establish an exclusion under the rule if the issuer's audited financial statements indicate that the issuer does not have the required amount of net tangible assets or average revenue at the date of the financial statements.

has been expanded to include certain transactions identified by the comments as being less in need of the protections provided by the penny stock disclosure rules.

1. Limited Broker-Dealer Activity in Penny Stocks

Section 15(g)(4) of the Exchange Act, which gives the Commission the authority to exempt any person or transactions from the rules adopted pursuant to section 15(g), requires the Commission to include an exemption for brokers-dealers that derive only an insignificant percentage of their total revenue from transactions in penny stocks. Accordingly, paragraph (a) of Rule 15g–1 exempts from Rules 15g–2 through 15g–6 transactions in penny stocks by broker-dealers that derive less than 5% of their total revenue from purchases and sales of penny stocks, except when they are acting as a market maker in the penny stock that is the subject of the transaction.

As adopted, the *de minimis* exemption differs from the proposed exemption in two significant respects. The 5% revenue calculation under the proposed rule was based on transactions in penny stocks, as defined in proposed Rule 3a51–1. A few comments pointed out that this would require broker-dealers to include in their 5% calculation transactions in low-priced securities that are issued by well-capitalized domestic and foreign issuers.[82] As a result, they indicated that the exemption would be too limited to be of much use to broker-dealers, even those broker-dealers that typically are not in the business of effecting transactions in penny stocks. In lieu of a transactional exemption, these comments recommended that the definition of penny stock include an exception based on the net tangible assets of the issuer.

As discussed above, to address the concerns expressed in these comment letters and to simplify the Rules, the Commission has amended the definition of penny stock in Rule 3a51–1 to exclude any security issued by an issuer that meets the financial standards set forth in paragraph (g) of that rule. Transactions in those securities therefore are not required to be included in the 5% revenue calculation for purposes of Rule 15g–1(a).[83] In addition, the rule has been revised to give broker-dealers the option of calculating their revenue over a six month period, rather than on a monthly basis.[84]

A few comments objected to the provision in Rule 15g–1(a)(2) that would preclude market makers from relying on the exemption because they believed that it would create a strong disincentive for securities firms to make markets in lower-priced securities.[85] The Commission, however, has determined to retain this provision because it believes that market making constitutes a level of involvement in the penny stock market inconsistent with the use of a *de minimis* exemption. The rationale for the *de minimis* exemption is that there is less risk of abuse from firms whose business is not concentrated on the penny stock market because they have less incentive or opportunity to manipulate the price of a penny stock. Conversely, much of the abuse in the penny stock market has involved market makers, because their ability to control the prices of the securities in which they make a market gives them the opportunity to generate large profits.[86] The Commission thus believes that it is appropriate to limit the *de minimis* exemption to firms that are not acting as market makers in penny stocks. This limitation is supported by fairness considerations; allowing larger firms to use the *de minimis* exemption while making markets in penny stocks potentially could provide them with an unfair competitive advantage over their smaller counterparts.[87] Therefore, regardless of their percentage of revenue from penny stock transactions, market makers in a penny stock are not exempt under Rule 15g–1 with respect to transactions in that particular penny stock.[88]

The Commission recognizes that broker-dealers relying on the *de minimis* exemption will need a period of time after the effective date of the Rules to modify their data retrieval systems in order to determine whether their revenue from penny stock transactions exceeds the 5% level.[89] The rule therefore includes a note indicating that broker-dealers may calculate their 5% revenue based on "designated securities," as defined in Rule 15c2–6(d)(2) (as of April 15, 1992), rather than "penny stocks," as defined in Rule 3a51–1, for a period of twelve months following the publication of this release in the **Federal Register**.

2. Institutional Accredited Investors

Proposed Rule 15g–1 provided an exemption for transactions with institutional accredited investors, as defined in Regulation D of the Securities Act.[90] No comments stated any

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[82] This is because, while transactions in such securities would have been exempt from the disclosure requirements of the rules, the securities would not have been excluded from the definition of penny stock in Rule 3a51–1.

[83] Two comments also recommended that the *de minimis* revenue exemption be expanded to reflect all revenues received by a broker-dealer. Conversely, one comment suggested that the exemption should be limited to commissions from agency trades. The Commission believes that the rule appropriately focuses on total sales-related revenue because it better identifies broker-dealers that have less incentive to engage in manipulative penny stock sales conduct. Thus, the rule as adopted applies to commissions, commission equivalents, mark-ups, and mark-downs.

Further, two other comments recommended exempting (or excluding) transactions effected by a broker-dealer acting as a dealer-manager or a financial advisor for an exchange offer, recapitalization, or restructuring. The Commission believes that most broker-dealers engaging in these activities may be exempt from the penny stock rules under the amended *de minimis* exemption. In this connection, the Commission emphasizes that advisory fees that are not contingent on the total volume of shares sold are not required to be included in the 5% revenue calculation for purposes of the rule.

[84] Specifically, subparagraph (a)(1) of the rule exempts transactions by a broker-dealer whose commissions, commission equivalents, mark-ups, and mark-downs from transactions in penny stocks during each of the immediately preceding three months and during eleven or more of the preceding twelve months, *or* during the immediately preceding six months, did not exceed 5% of its total commissions, commission equivalents, mark-ups, and mark-downs from transactions in securities during those months.

[85] The CFA, on the other hand, strongly supported this provision.

[86] For further discussion of price manipulation by market makers in thinly traded markets, see Proposing Release, 56 FR 19175; Rule 15c2–6 Release, 54 FR 35477; and House Report at 11–12.

[87] For this reason, two comments opposed the *de minimis* revenue exemption in principle.

[88] For the reasons discussed above, however, broker-dealers will now be able to act as market makers in securities whose issuers meet the financial standards set forth in Rule 3a51–1(g), without jeopardizing their ability to rely on the *de minimis* exemption.

[89] In particular, broker-dealers may need to modify their systems to take into account the fact that the *de minimis* exemption under Rule 15g–1 is different from the analogous exemption under Rule 15c2–6 because it is based on transactions in "penny stocks," as defined in Rule 3a51–1, rather than transactions in "designated securities," as defined in subparagraph (d)(2) of Rule 15c2–6. Specifically, the exemption under Rule 15g–1 is broader than the exemption under Rule 15c2–6 in that it allows broker-dealers to exclude from their 5% calculation securities priced below five dollars. In addition, unlike Rule 15c2–6, which permits broker-dealers to exclude transactions in securities if the issuer has $2 million in net tangible assets, Rule 15g–1 only allows broker-dealers to exclude those transactions if the issuer has been in business for at least three years. Rule 15g–1, however, allows broker-dealers to exclude transactions based on average revenues of the issuer. Finally, because the penny stock disclosure rules apply to both purchases and sales of penny stocks, the *de minimis* revenue exemption under Rule 15g–1 includes mark-downs in the 5% calculation.

[90] 17 CFR 230.501(a)(1), (2), (3), (7), or (8). Under these provisions, an "accredited investor" is defined as:

Any bank as defined in section 3(a)(2) of the [Securities] Act, or any savings and loan association or other institution as defined in section 3(a)(5)(A) of the Act whether acting in its individual

Continued

objection to this provision. Therefore, for the reasons stated in the Proposing Release, the Commission has determined to include the exemption in paragraph (c) of the adopted rule.[91]

3. Private Offerings

Although proposed Rule 15g–1 included an exemption for transactions with institutional accredited investors, it did not provide a similar exemption for individual accredited investors.[92] The Proposing Release specifically requested comment on whether transactions with individual accredited investors also should be exempt from the penny stock disclosure rules. In response, several comments argued that there are insufficient grounds for distinguishing between institutional and individual accredited investors, especially in light of the fact that the two types of investors are treated in the same manner under Regulation D of the Securities Act. They therefore suggested exempting all accredited investors from the Rules.

The Commission has determined not to provide a general exemption for transactions with individual investors based solely on their net worth or income. Unlike institutional investors, which generally do not purchase penny stocks, individual accredited investors are frequently the target of high pressure sales efforts involving speculative equity securities. Given the lack of publicly available information about the price and trading volume of particular penny stocks and the penny stock market in general, these investors often have few means of independently evaluating the market for the stock in question or the financial interest of the broker-dealer in the transaction. In the absence of this information, many individual investors of considerable financial means have been convinced through abusive sales practices to purchase penny stocks without sufficiently understanding the nature of the market. The penny stock disclosure rules are designed to give individual investors the information they need to make an independent and informed evaluation of a broker-dealer's recommendation to invest in low-priced securities that are not traded in a visible public market.[93]

The Commission recognizes, however, that many of the sales practice abuses that occur in the secondary market for penny stocks do not occur in initial private offerings. In general, private offerings are limited to a small number of investors who are familiar with the broker-dealer involved in the transaction and who have access to information about the issuer of the securities.[94] In addition, securities that are sold in private placements are subject to certain restrictions on resale.[95] As a result, the market for these securities is limited and the securities typically are not used as vehicles for the types of market manipulation and broad scale sales efforts characteristic of fraudulent penny stock activities.

Accordingly, the list of transactions that are exempt under Rule 15g–1 has been expanded to include an exemption for transactions that meet the requirements of Regulation D under the Securities Act,[96] as well as transactions by an issuer not involving any public offering pursuant to section 4(2) of the Securities Act.[97] Assuming that the requirements of either of those provisions have been met, this exemption applies even if the particular customer involved is not an accredited investor.

4. Insider Transactions

Under proposed Rule 15g–1, transactions by issuers repurchasing or redeeming their own securities were exempt on the basis that corporations have sufficient access to information about the market for their own securities to deal with broker-dealers without the additional disclosure provided by the Rules. Several comments suggested that, in addition to the issuer of the penny stock, officers, directors, and controlling shareholders of the issuer should be exempt from the Rules because, as insiders, they also have sufficient knowledge about the issuer to be aware of the risks of their investment. As one broker-dealer stated, "insiders would have a * * * better knowledge of the intrinsic value of the security than any market-maker, and should not require the protection of this rule."[98] The Commission agrees with these comments and therefore has expanded the issuer exemption in Rule 15g–1 to also exempt from Rules 15g–2 through 15g–6 transactions in which the customer is a director, officer, general partner, or direct or indirect beneficial owner of more than 5% of any class of equity security,[99] of the issuer of the penny stock that is the subject of the transaction.

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or fiduciary capacity; any broker or dealer registered pursuant to section 15 of the Securities Exchange Act of 1934; any insurance company as defined in section 2(13) of the Act; any investment company registered under the Investment Company Act of 1940 or a business development company as defined in section 2(a)(48) of that Act; any Small Business Investment Company licensed by the U.S. Small Business Administration under section 301(c) or (d) of the Small Business Investment Act of 1958; any plan established and maintained by a state, its political subdivisions, or any agency or instrumentality of a state or its political subdivisions, for the benefit of its employees, if such plan has total assets in excess of $5,000,000; any employee benefit plan within the meaning of the Employee Retirement Income Security Act of 1974 if the investment decision is made by a plan fiduciary, as defined in section 3(21) of such Act, which is either a bank, savings and loan association, insurance company, or registered investment adviser, or if the employee benefit plan has total assets in excess of $5,000,000 or, if a self-directed plan, with investment decisions made solely by persons that are accredited investors;

Any private business development company as defined in section 202(a)(22) of the Investment Advisers Act of 1940;

Any organization described in section 501(c)(3) of the Internal Revenue Code, corporation, Massachusetts or similar business trust, or partnership, not formed for the specific purpose of acquiring the securities offered, with total assets in excess of $5,000,000;

Any trust, with total assets in excess of $5,000,000, not formed for the specific purpose of acquiring the securities offered, whose purchase is directed by a sophisticated person as described in 230.506(b)(2)(ii); and

Any entity in which all of the equity owners are accredited investors.

For further discussion of the definition of accredited investor, see Securities Act Release No. 6825 (March 20, 1989), 54 FR 11369.

[91] See 56 FR 19177.

[92] The term "individual accredited investor" is defined in 17 CFR 230.501(a)(4), (5), and (6) as:

Any director, executive officer, or general partner of the issuer of the securities being offered or sold, or any director, executive officer, or general partner of a general partner of that issuer;

Any natural person whose individual net worth, or joint net worth with that person's spouse, at the time of his purchase exceeds $1,000,000; or

Any natural person who had an individual income in excess of $200,000 in each of the two most recent years or joint income with that person's spouse in excess of $300,000 in each of those years and has a reasonable expectation of reaching the same income level in the current year.

[93] See Proposing Release, 56 FR 19177, n. 101. As the State of Missouri pointed out in its comment letter, "[t]he information reported on a weekly basis in a few major newspapers is not sufficient disclosure for the average investor in penny stocks in this state, who is often a first-time investor, almost always unsophisticated * * *." Rules 15g–2 through 15g–6 are specifically designed to redress this information imbalance by requiring broker-dealers to disclose information regarding the risks involved in investing in the penny stock market, quotations and other relevant market information, including monthly account statements, and the amount of compensation received by the broker-dealer and any associated persons of the broker-dealer in connection with the penny stock transaction. See discussion at sections III.C–G, *infra*.

[94] *See SEC* v. *Ralston Purina Co.*, 346 U.S. 119 (1953) (in determining whether a distribution was a private offering exempt under section 4(2) of the Securities Act, the Supreme Court focused on the offerees' need for the protections of the Securities Act—namely, whether they were able to "fend for themselves" and had access to the same kind of information that usually is disclosed through registration).

[95] See, *e.g.*, 17 CFR 230.502(d).

[96] 17 CFR 230.501 through 230.508.

[97] 15 U.S.C. 77d(2).

[98] Herzog, Heine, Geduld, Inc.

[99] The 5% figure is derived from Rule 13d–1(a) (17 CFR 240.13d-1(a)) of the Exchange Act.

5. Non-Recommended Transactions

Proposed Rule 15g–1 contained an exemption for transactions in penny stocks that are not recommended by a broker-dealer. All of the comments that addressed this provision supported the concept of an exemption for non-recommended transactions. Several comments, however, requested that the Commission clarify the scope of the exemption by distinguishing between retail broker-dealers who actively recommend stocks to individual investors and wholesale market makers who maintain lists of the types or specifications of stocks in which certain active investors have expressed an interest. These comments argued that the activities of wholesale broker-dealers should be considered "non-recommended" because the customers of those broker-dealers make their own investment decisions once they are alerted to the existence of a stock that meets their specifications.[100] Two commenters believed that the exemption would be clearer if it applied to non-solicited, rather than non-recommended, transactions.

The Commission has determined to retain the exemption for non-recommended transactions in paragraph (e) of Rule 15g–1. To be consistent with Rule 15c2–6, the exemption continues to apply to "non-recommended" rather than "non-solicited" trades.[101] Accordingly, the exemption is limited to situations in which a broker-dealer acts as an order taker for the customer, with little or no incentive to engage in manipulative sales tactics. The rule does not exempt situations in which a broker-dealer brings a penny stock to the attention of an investor because, in most cases, this action is intended, and is understood by the customer, as an implicit recommendation to buy the penny stock. Moreover, as a practical matter, the Commission believes that it would be difficult to determine whether a broker-dealer "brought a penny stock to the attention of a customer," or whether it actively promoted the merits of that penny stock. In any case, wholesale market makers who maintain lists of stocks that they bring to the attention of institutional investors generally will be able to rely on the exemption for transactions with institutional accredited investors under paragraph (b) of Rule 15g–1.[102]

6. Exemptive Authority

Finally, as in the proposed rule, Rule 15g–1 includes a provision giving the Commission the authority to exempt by order any transaction or persons or class of persons from Rules 15g–2 through 15g–6 if it determines that an exemption would be consistent with the public interest and the protection of investors. The Commission believes that this provision will give it the necessary flexibility to exempt transactions and persons that are subject to alternative disclosure requirements that are comparable to the requirements of the Penny Stock Act.[103]

C. Rule 15g–2: Penny Stock Risk Disclosure Document

Section 15(g)(2) of the Exchange Act requires a broker-dealer to provide to each of its customers, prior to effecting any transaction in any penny stock, a document that discloses the risks of investing in the penny stock market. The statute enumerates the following specific items that broker-dealers must include in the disclosure document: (i) A description of the nature and level of risk in the market for penny stocks in both public offerings and secondary trading; (ii) a description of the broker-dealer's duties to the customer and of the customer's rights and remedies; (iii) a brief, clear, narrative description of a dealer market, including 'bid' and 'ask' prices for penny stocks and the significance of the spread between the bid and ask prices; (iv) the NASD's toll-free telephone number for inquiries on disciplinary actions; and (v) definitions of significant terms.[104] The statute grants the Commission specific rulemaking authority with respect to the language and the type size and format to be used in the risk disclosure document.[105] In enacting section 15(g)(2), Congress recognized that basic information about the nature of the penny stock market, its depth and liquidity, and the risks of investing, is largely unavailable to many investors.[106]

1. Description of the Rule

Pursuant to this statutory authority, the Commission is adopting Rule 15g–2. The rule makes it unlawful for a broker-dealer to effect a transaction in a penny stock with or for the account of a customer unless the broker-dealer distributes to the customer, prior to effecting a transaction in a penny stock,[107] a two-part document, as set forth in Schedule 15G.

The first part of the risk disclosure document, entitled "Important Information on Penny Stocks" (the "Summary Document"), summarizes on a single page the items required to be disclosed pursuant to section 15(g)(2). The preamble urges investors to read the risk disclosure document before purchasing a penny stock. The first section of the Summary Document, entitled "Penny stocks can be very risky," briefly defines "penny stock" and identifies certain risks of investing in penny stocks. The second section, entitled "Information you should know," describes the penny stock market and

[100] In Mayer & Schweitzer, Inc.'s view, "[t]he trader does not recommend such security to the customer. The trader is merely telling the customer that such stock is available and asks whether the customer has any interest in such security."

[101] The Commission's interpretation of the "non-recommended" transaction exemption under Rule 15c2–6 therefore applies to the exemption in paragraph (e) of Rule 15g–1. Under this interpretation, neither exemption would apply to situations in which a broker-dealer recommends a penny stock by sending promotional literature directly to a particular investor. For further discussion of what constitutes a "recommended" transaction, see Rule 15c2–6 Release, 54 FR 35477.

[102] In addition, two comments suggested that the exemption should be expanded to include sales or other transactions that primarily are effected to avoid customer losses, such as "liquidating transactions." The Commission has not adopted this suggestion because it believes that in most cases it would be difficult to determine whether a transaction was effected solely to avoid customer losses—especially when one penny stock is sold in exchange for another penny stock. Moreover, the information provided by the penny stock rules, particularly Rule 15g–3 (disclosure of quotation information), will assist investors in determining whether to sell a penny stock to avoid a loss.

[103] The Commission also has the authority under section 15(g)(4) of the Exchange Act to exempt any person or transaction from the disclosure requirements by rule or regulation.

[104] 15 U.S.C. 78*o*(g)(2).

[105] See 15 U.S.C. 78*o*(g)(2)(F).

[106] Section 15(g)(2) reflects the Congressional finding that broker-dealers in the penny stock market have sold stock to investors with little sophistication or understanding of that market. See Proposing Release, 56 FR 19180.

[107] As noted in the Proposing Release, in practice, the broker-dealer probably would send the disclosure document to a potential customer through the mail after preliminary telephone contact; however, the document also could be provided to a potential investor in the course of a meeting, before the investor agrees to the penny stock trade. In any event, a broker-dealer would be obligated to ensure that each customer has received the document before effecting the first transaction in a penny stock with the customer. "Effecting" in this context means agreement, oral or otherwise, to the terms of the transaction.

In response to one comment requesting clarification whether the risk disclosure document must be provided prior to effecting every transaction in a penny stock, the Commission notes that, by its terms, the Penny Stock Act only requires provision of the document to the customer prior to a broker-dealer's effecting *any* transaction in a penny stock. Thus, once the customer has received the document prior to the first transaction, in any subsequent transaction by the broker-dealer with that customer, the broker-dealer will be in compliance with the rule. However, broker-dealers are encouraged to provide a new copy of the risk disclosure document to the customer prior to effecting another transaction if a substantial amount of time has elapsed since the previous transaction.

terminology important to an understanding of that market. The final section, entitled "Brokers' duties and customers' rights and remedies," informs customers who have questions or who have been defrauded that they may have rights or remedies under federal and state law, and provides a toll-free telephone number of the NASD and the central number of NASAA for information on the background and disciplinary history of the firms and salespersons with whom they are dealing, and the Commission's complaint number.

The remainder of Schedule 15G (the "Explanatory Document") supplements and explains in greater detail the information provided in the Summary Document. The Explanatory Document begins with a section entitled "Further Information," [108] which provides a non-technical definition of "penny stock," and gives several warnings to investors concerning the penny stock market, including warnings against making a hurried investment decision, that salespersons are not impartial advisers, that investors should compare information from the salesperson with other information on the penny stock, and that salespersons may not legally state that a stock will increase in value or guarantee against loss. This section also discusses "shell" corporations, the high risks of initial public offerings, the speculative nature of penny stocks and the potential for significant losses, and suggests contacting the NASD and NASAA to obtain information on salespersons and broker-dealers and reading the prospectus in a public offering before making an investment. Investors are further informed that they do not have to transfer their stock if their salesperson leaves the firm and that they have the right to physical possession of their stock certificates.

The next section of the Explanatory Document, entitled "Your Rights," informs investors about their rights and the broker-dealer's duties under the new penny stock rules, including the particular disclosures that must be made to them under each rule, and of the timing requirements for such disclosures. The section also informs customers generally of their rights under section 29(b) of the Exchange Act, as amended by the Penny Stock Act, which may allow a rescission of the purchase contract for broker-dealer transactions in violation, *inter alia*, of the disclosure rules under section 15(g) of the Exchange Act. Customers also are informed of the availability of private litigation if they believe they have been defrauded or their rights otherwise violated, and the use of arbitration procedures, if they are subject to an arbitration agreement, and that they can report their grievances to regulatory authorities, including the Commission, the NASD, and their state securities administrator.

The final section of the Explanatory Document, entitled "Market Information," provides an overview of important aspects of the market for low-priced securities. The first two paragraphs provide a general description of the non-NASDAQ market and an explanation of important concepts associated with that market, such as the role of brokers, dealers, and market makers, and the ability of firms in the penny stock market to dominate the market in a penny stock and to control its prices. The next three paragraphs provide a detailed explanation of the relationship between mark-ups, mark-downs, the dealer's spread, and broker-dealer compensation, and discuss the reason why the bid price of a low-priced stock purchased by a customer generally must rise substantially before the customer may profitably resell that stock. The final two paragraphs explain the initial public offering, warn investors of the especially high risk in such a market, and provide the Commission's address for investors who want additional information concerning penny stocks.

Schedule 15G contains instructions for production of the document by the broker-dealer. The instructions set forth the criteria for type size and typeface, so that the document will be uniform among broker-dealers, and so that the type will be sufficiently large to be legible to the average reader. [109] Schedule 15G may be reproduced by photographic copying, so long as the copy is clear, complete, and meets the minimum type size requirements set forth for a printed document. In addition, the instructions prohibit the broker-dealer from omitting, adding to, or altering the language of Schedule 15G in any way and from providing supplementary materials to the customer intended to detract from, rebut, or contradict Schedule 15G. Broker-dealers may not charge customers a fee for receipt of Schedule 15G. In addition, broker-dealers are required to distribute the Summary Document as the first page of the risk disclosure document, and on one page only.

2. Schedule 15G as Proposed

Schedule 15G as originally proposed consisted of a three-part document, entitled "Penny Stock Disclosure Document," that outlined the items broker-dealers are required to disclose pursuant to the Penny Stock Act. The document defined a penny stock, provided several brief warnings to investors, discussed the disclosures required by the proposed penny stock disclosure rules and the available legal remedies under the section entitled "Your Rights," and, under the caption "Important Market Information," explained the functioning of the penny stock market. Specific features of the proposed rule are discussed below in connection with the comments.

3. Simplification

In the Proposing Release, the Commission requested comment whether the language of Schedule 15G as proposed accurately and concisely communicated the information required by the Penny Stock Act. While nearly all comments expressed general agreement with the philosophy of providing a risk disclosure document to customers in penny stock transactions, many comments also said that the schedule was too complicated for the average investor to read and comprehend. [110] Along the same line, some comments argued that a one-page document would achieve the purpose of a risk disclosure document more effectively. Three comments pointed to the risk disclosure document required under the

[108] Included at the beginning of the Explanatory Document is a statement that the Commission has not approved or disapproved the securities being sold or offered for sale, and has not passed upon the fairness or merits of the transaction or the accuracy or adequacy of the information contained in any prospectus or otherwise provided by a broker-dealer. This proposed statement is similar to notices required by Rule 13e-3 under the Exchange Act (17 CFR 240.13e-3(e)(3)(ii) (A) and (B)), Item 431 of Regulation C under the Securities Act (17 CFR 230.481(b)(1)), and Item 501 of Regulation S-K under the Securities Act (17 CFR 229.501(c)(5)). See also, e.g., Regulation A, 17 CFR 230.610a, Item 1, part (e), and Division I, Item 2, of Schedules A, B, C and D to Regulation B, 17 CFR 230.300-346.

[109] The fonts required by the Schedule are consistent with those used for other documents required to be produced under the Securities Act and Exchange Act. See, *e.g.*, the printing instructions set forth in Regulation S-K under the Securities Act, 17 CFR 229.501(c)(5), and Rule 13e-3 under the Exchange Act, 17 CFR 240.13e-3(e)(3)(ii)(A) and (B).

[110] One comment stated that proposed Schedule 15G required a level of sophistication that the average penny stock investor lacks, and that the document should not exceed the average adult reading comprehension level in this country. Other comments pointed to specific portions of the document, stating that they should be rewritten, either to clarify or to simplify the language.

Commodity Exchange Act,[111] which informs investors of the risks involved in trading commodity futures contracts in five brief paragraphs, as a good example.

In response to the comments, the Commission has revised Schedule 15G to make it more straightforward and comprehensible to the average reader. First, the Commission has added the new Summary Document to summarize the essential information. The Commission believes that a brief, one-page document, which succinctly states the main required items, would more effectively attract the average investor's attention.

Second, the Commission has revised Schedule 15G as proposed, which has become the Explanatory Document as described above. Changes from proposed Rules 3a51–1 and 15g–1 through 15g–6 are reflected in the Explanatory Document. Where possible, without altering significantly the meaning of Schedule 15G as proposed, shorter, more commonly understood words have been substituted. Most paragraphs have been shortened; however, to incorporate some of the comments noted below, the Commission has expanded other sections.

4. Strengthening the Risk Disclosure Document

The Commission has accepted several suggestions proposed in the comment letters intended to strengthen the risk disclosure document. In response to one recommendation, the Commission has revised the discussion of the relationship between the bid and offer quotation prices, the spread, and the compensation of a broker-dealer.[112] Investors are warned that, in order to sell their stock at a profit, the bid price must rise above both the original offer price (constituting the dealer's spread), and the compensation to the broker-dealer, consisting of the mark-up in the original transaction and the mark-down in the sales transaction.

The Commission also has included the Commission's own telephone number for reporting complaints and NASAA's central telephone number in addition to the NASD toll-free telephone number. Investors may call the latter two numbers for the disciplinary history of broker-dealers and their salespersons.[113]

Several comments suggested broadening the description of the penny stock market to include the Bulletin Board, and other local or regional interdealer quotation services. The Commission has added the Bulletin Board to the description of the quotation media in which information about penny stocks may be obtained.

One comment suggested that prior to a transaction, investors should be required to sign and return a form to the broker-dealer stating that they had read the risk disclosure document. The Commission believes that the burden on broker-dealers of imposing such a requirement would be too high, both in terms of the delay in effecting a transaction, and the additional paperwork involved. Instead, compliance with the rule may be monitored by review of the broker-dealer's internal procedures, and, if necessary, by contacting the clients of the broker-dealer.

Similarly, the Commission also has decided against requiring the firm to provide the risk disclosure document to all investors in penny stocks, including those investing in transactions exempted by Rule 15g–1,[114] as proposed by one comment. For the reasons stated in the Proposing Release, the Commission believes that such a requirement is not warranted.[115] Under the definition of a penny stock as set forth in Rule 3a51–1 as adopted, transactions in a stock registered and executed on a national securities exchange or quoted on NASDAQ are excluded from Rule 15g–2, in addition to the other penny stock disclosure rules being adopted today.[116] The availability of price and volume information in these markets enhances the ability of investors to investigate the accuracy of their broker-dealer's or salesperson's representations. Moreover, SRO rules impose certain restrictions on these quotations designed to protect investors.[117] The Commission believes that investors would not receive significantly greater protection from receiving a risk disclosure document in such transactions.

Several representatives from the industry felt that the risk disclosure document casts the penny stock market in an unduly pejorative light.[118] One broker-dealer stated that the term "penny stock" should not be used because its negative connotation may taint all securities that technically fall within that category. However, the objective of the risk disclosure document, as reflected in the Penny Stock Act and its legislative history, is to disclose the risks present in this market as well as the incidence of fraud that has been demonstrated. After reviewing the risk disclosure document, and making the revisions described above, the Commission believes that this document, which is necessarily a warning notice, achieves this objective in a measured way.[119]

D. Rule 15g–3: Broker-Dealer Disclosure of Quotations and Other Information Relating to the Penny Stock Market

The Penny Stock Act requires the Commission to adopt a rule requiring broker-dealers to disclose to each customer, prior to effecting any transaction in, and at the time of confirming any transaction with respect to any penny stock, the bid and ask prices for the penny stock, and the

[111] See 17 CFR 1.55. Rule 1.55, adopted by the Commodity Futures Trading Commission under the Commodity Exchange Act, 7 U.S.C. 1 *et seq.*, requires futures commissions merchants and introducing brokers, before opening an account, to receive from their customer a signed and dated acknowledgment that the customer has received and understood a risk disclosure statement that contains only the language set forth in the rule.

[112] A substantial portion of the Summary Document is devoted to this subject.

[113] The Commission has not included a description of the type of disciplinary history available from the NASD and NASAA, as some comments had suggested. The Commission believes that such a specific explanation might be confusing to the ordinary investor. The Summary Document simply indicates that "additional information" may be obtained from NASAA.

[114] See Section III.B of this release. In contrast, another comment suggested that the obligation to deliver the document be restricted to purchasers of a penny stock, because of the limited benefits of providing the document to customers who are only selling penny stocks. However, the Commission notes that the Penny Stock Act does not distinguish between purchasers and sellers in a penny stock transaction. In addition, the document contains important warnings not only to purchasers, but also to sellers, of penny stocks.

[115] See Proposing Release, 56 FR 19178.

[116] See paragraphs (e) and (f) of Rule 3a51–1.

[117] See, *e.g.*, NASD Rules of Fair Practice, Art. III, Section 5, *NASD Manual* (CCH) ¶ 2155 (NASD member prohibited from publishing any notice quoting a bid or offer price for a security, unless it believes that such quotation represents a *bona fide* bid or offer).

[118] One comment argued that the language in proposed Schedule 15G would lead investors to believe that there was no legitimate penny stock activity. Another comment said that the schedule concluded that a dominated market is inherently a fraudulent market.

[119] In this connection, instructions to proposed Schedule 15G stated that no language of the document may be omitted, added to, or altered in any way. Some comments requested clarification whether the document nonetheless may be supplemented by additional materials. One comment strongly encouraged that such a practice be permitted, and that the prohibition on changes be restricted only to the document itself.

In response, the Commission has included specific language warning broker-dealers against supplementing Schedule 15G with any material intended in any way to detract from, rebut, or contradict the risk disclosure document. The Commission believes that supplementary materials intended to reduce the impact of the risk disclosure document potentially could undermine the purpose of the risk disclosure document to alert investors to the high pressure and abusive sales tactics in the penny stock market, as reflected in Congressional findings and in Commission proceedings.

number of shares to which such bid and ask prices apply.[120] If information is not available on bid and ask prices, broker-dealers must provide customers with other useful and reliable information relating to prices of penny stock, and other comparable information relating to the depth and liquidity of the market for the stock.[121]

1. Description of the Rule

Pursuant to this statutory requirement, Rule 15g–3 requires a broker-dealer that effects a transaction in any penny stock with or for the account of a customer to disclose to its customers, prior to effecting the transaction, and in the written confirmation,[122] certain information relating to prices and quotations. Procedures for disclosing quotations derived from interdealer bid and offer prices are treated separately in principal transactions on the one hand, and riskless principal and agency transactions, on the other.

The rule sets forth three levels of disclosure in principal transactions, other than riskless principal transactions,[123] depending on the availability and reliability of price information. First, paragraph (a)(1) of Rule 15g–3 requires a broker-dealer effecting a transaction in a penny stock to provide the inside bid and offer quotations for the penny stock appearing on a Qualifying Electronic Quotation System, such as the Bulletin Board, on which there is both an inside bid and offer quotation for the security.[124]

Second, if an inside quotation, as defined, is not available, the rule requires disclosure of the broker-dealer's own quotations. For principal transactions other than riskless principal transactions, a broker-dealer is required to disclose its own bid and offer prices if, during the previous five business days, the dealer has effected at least three *bona fide* sales to, in the case of its current offer quotation, or purchases from, in the case of its current bid quotation, other dealers consistently at these respective bid or offer quotations at the time of those transactions.[125] In addition, the dealer must reasonably believe in good faith at the time of the transaction with the customer that its respective bid or offer price accurately reflects the price at which it is willing to sell to or buy from other dealers.[126]

In order for a quotation to be disclosed under this second procedure, no less than 75% of a broker-dealer's *bona fide* interdealer purchases or sales must have occurred consistently at the currently quoted price over the previous five-day period. At a minimum, dealers must have effected three *bona fide* transactions with other dealers. If only three interdealer transactions have occurred in the interdealer market, all three such transactions must have occurred at the dealer's currently quoted bid or offer price, as the case may be.

Finally, if the dealer's own bid and offer prices differ from its interdealer transaction prices over the previous five days, the rule requires the dealer to disclose that it has not consistently effected interdealer purchases or sales of the penny stock at its bid or offer price. The dealer also must disclose to the customer the price at which it last purchased the penny stock from, or sold the penny stock to, respectively, another dealer in a *bona fide* transaction.

In this situation, the dealer must state, in a clear manner, the price of its last transaction and its lack of trades consistent with its quotes. The Commission believes that under such circumstances it generally would be misleading to customers for dealers to provide, in addition, their own purported market quotations, since the broker-dealer's own quotes would not reflect the prices at which it is trading. If the dealer nonetheless chooses to provide additional quotations, such quotations must be *bona fide*, and the dealer must communicate clearly the nature of those quotations, without rendering the required disclosures ineffectual.[127]

In the case of a sole market maker in a penny stock, the market maker would be required to disclose its quotations, if validated by its trades, as required by the rule. Otherwise, it must disclose its last relevant trade price, and the fact that its trades and quotes were not consistent. In other instances where it has not been possible for a dealer to effect transactions consistently with other dealers over a five-day period, as, for example, during the first few days of an initial public offering, a dealer would be required to disclose to the customer that it has not effected previous, consistent interdealer purchases or sales. In the case of an initial public offering, the broker-dealer could explain that no trading market existed prior to the offering. This information should indicate to the customer that the market for the securities may be inactive or untested, because an interdealer market has not yet been established for the securities.

The rule provides for a separate procedure for disclosing transactions effected by a broker on an agency basis, or by a broker-dealer on a riskless principal basis. In these trades, the rule requires a broker-dealer to disclose the best interdealer bid and offer prices for the penny stock that the broker-dealer obtains through reasonable diligence. The Commission believes that the "reasonable diligence" standard would require the broker-dealer acting as agent or riskless principal, at a minimum, to follow standards set forth by the NASD, and generally accepted as industry practice, by presenting to the customer the best of three quotations obtained from market makers in the security. Quotations from all market makers

[120] 15 U.S.C. 78o(g)(3)(A)(i), (ii).

[121] *Id.*

[122] The timing and procedure of disclosure are discussed at Section III.G of this release.

[123] Riskless principal transactions are discussed below in this section in connection with the comments to Rule 15g–3 and in Section III.E in connection with Rule 15g–4. For purposes of these rules, riskless principal transactions are those trades for which the dealer has both a buy and a sell commitment at the time of the trade with the customer.

[124] The Penny Stock Act provides that the Commission shall facilitate the development of automated quotation systems that collect and disseminate information regarding penny stocks. A "Qualifying Electronic Quotation System" is defined in paragraph (c)(5) of the rule. See the discussion of this system below in this section.

[125] Under this validation procedure, the broker-dealer is required under the rule to disclose to the customer both its bid and offer quotations for a penny stock. However, the Commission wishes to clarify that in order to do so, the validation procedure under Rule 15g–3 does not require the dealer to have effected both three sale and three purchase transactions in the previous five days. It is sufficient that only one side, *i.e.*, either the bid or the offer side, be validated. For example, a dealer may have effected only three sales, and no purchases, of a penny stock during the relevant period. Nevertheless, provided that the other elements of the validation procedure have been satisfied, the dealer would give its own bid and offer quotations to the customer in satisfaction of the requirements of Rule 15g–3.

However, if any transaction(s) has occurred on the other side in the relevant five-day period, the dealer must have effected such transaction(s) at its quoted price at the time of such transaction(s), and the 75% standard would apply. The three transaction requirement would not apply in determining consistency of transactions at the quoted price on this other side.

[126] In reviewing the quotations disseminated by dealers under the rule that are validated by interdealer transactions, the Commission intends to consider the context in which such interdealer transactions have occurred to determine whether the interdealer transactions are *bona fide*, *i.e.*, whether such transactions are arms-length and otherwise determined by market forces.

[127] When making such additional quotations under paragraph (a)(2)(i)(C) of Rule 15g–3, the dealer must, at a minimum, communicate clearly to the customer that the dealer has not consistently effected such interdealer purchases or sales at its bid or offer for the number of shares to which the bid and offer apply and that the dealer's quotations under these conditions are potentially unreliable.

would have to be provided if there are fewer than three.[128]

Finally, paragraph (a)(3) of the rule requires broker-dealers to disclose the number of shares to which the bid and offer prices apply.[129]

2. Comments on Rule 15g–3

The Commission requested comment concerning the procedure for validating quotations of broker-dealers, specifically, the adequacy and appropriateness of the provision of the proposed rule requiring that at least 75% of a dealer's purchase or sales transactions during the previous five-day period occur at its bid or offer price. Six comments supported the manner in which the rule requires disclosure of quotations.[130] However, representatives of industry generally were critical of the validation process, stating that it posed substantial compliance and operational problems.[131] In particular, these comments asserted that it would be unduly burdensome for broker-dealers to determine whether quotations were "consistent" during the five-day period prior to effecting the penny stock transaction. The NASD stated that the 75% figure was too high, and would be ineffective without a minimum number of trades. The NASD preferred a process of validation based on *Alstead, Dempsey & Company, Inc.* ("*Alstead*"),[132] which permits use of properly validated quotations in the absence of contemporaneous transactions, without quantifying the percentage of trades required to validate the quotations.

In response to these comments, the Commission has concluded that broker-dealers should have available an objective procedure that would assist them in complying with the Penny Stock Act's requirement of disclosure of bid and offer quotations. In section 17B of the Exchange Act, Congress directed the Commission to facilitate the "wide-spread dissemination of reliable and accurate last sale and quotation information with respect to penny stocks," which would provide, among other things, bid and offer quotations of participating broker-dealers, or other comparably accurate and reliable pricing information. The Commission has incorporated the standards enumerated in section 17B in the specifications of an automated quotation system for purposes of disclosure under Rule 15g–2.[133] The Commission believes that the use of such a quotation system will substantially ease the costs to broker-dealers of complying with the bid-offer disclosure requirement of the Penny Stock Act.

The rule requires use of the highest firm inside bid quotation and the lowest firm inside offer quotation displayed on a Qualifying Electronic Quotation System, when available.[134] Under paragraphs (c)(3)–(4) of the rule, in order for an "inside bid quotation" and an "inside offer quotation" to exist, at least two market makers in the security must contemporaneously be displaying on a Qualifying Electronic Quotation System bid and offer quotations for the security at specified prices.[135] Consequently, broker-dealers will provide these publicly disseminated quotations in the pre-trade disclosure and in the confirmation by drawing these quotes electronically from an external data source. The Commission believes that broker-dealers should be able to derive the inside quotes from an electronic system like the Bulletin Board in an efficient and straightforward manner, and that this will provide useful information to investors.

In its comment letter, the ABA hypothesized a situation where a broker-dealer has consistently effected *bona fide* sales to other dealers at its offer price, but has not effected purchases consistently at its bid price. The letter argued that this "unfairly" required the broker-dealer to disclose the unreliability of its quotations to its customers. However, one of the principal reasons for requiring broker-dealers to disclose bid as well as offer quotations is so that investors understand the problems that they may face when they attempt to sell a penny stock. A consistent bid price, validated by actual trades, evidences an active, liquid secondary market in the stock, and, therefore demonstrates that the customer may readily find a broker-dealer to repurchase that stock.

3. Validation of Quotations in Principal Transactions

Where qualifying inside quotations are not available, however, the Commission has retained the proposed validation procedure, while modifying certain features in accordance with the comments. The Commission believes that outside of an electronic quotation environment with multiple displayed quotations, quotations in the non-NASDAQ OTC market are not sufficiently reliable to require broker-dealers to give them to customers without a validation process. Moreover, as an operational matter, based on the comment letters and discussions with a number of broker-dealers, it appears that market makers generally are aware whether they are trading at their quoted prices. Although the Commission considered using a non-quantified validation standard, as suggested by the NASD, the Commission believes that a validation standard provides clearer

[128] See Interpretation of the Board of Governors, *NASD Manual* (CCH) ¶ 2151.03, Interpretation D, at 2037–3. Interpretation D reads as follows:

In any transaction for or with a customer pertaining to the execution of an order in a non-NASDAQ security (as defined in Schedule H to the By-Laws), a member or person associated with a member, shall contact and obtain quotations from three dealers (or all dealers if three or less) to determine the best inter-dealer market for the subject security.

The Commission notes that in any transaction in which a broker-dealer is acting in an agency or riskless principal capacity, the firm generally would have at least one *bona fide* quote to provide to a customer. In such transactions, the broker-dealer would obtain the security contemporaneously from another broker-dealer at a quoted price, and thus would be able to provide that quote to its customer. Therefore, the rule does not contain a provision requiring a broker-dealer in agency or riskless principal transactions to disclose the unreliability of quotation information. In contrast, in principal transactions not effected on a riskless principal basis, a dealer may sell the security from its inventory when no readily ascertainable quote is available. In such instances, the rule requires disclosure of the unreliability of unvalidated quotes.

[129] The Commission believes that the general antifraud provisions of the federal securities laws would prohibit the dealer from providing a quotation, such as for a round lot of shares, without further explanation if the broker-dealer is aware that this quotation in fact would mislead the customer with respect to the value actually paid or received by the customer in a transaction resulting from such a quotation.

[130] According to one comment, the rule as proposed would contribute substantially to the investor's ability to make an informed choice about the advisability of investing in a penny stock.

[131] One comment stated that the validation procedure would render automated back office services useless for processing penny stock transactions, but did not specify how this would be the case.

Some comments queried whether the bid and offer information required at the time of confirmation is the quotation information disclosed at the time of the pre-trade disclosure, or at the time of the confirmation. In the post-trade confirmation, the bid and offer quotation information would be the same bid and offer information disclosed pursuant to the pre-trade disclosure requirement.

[132] 47 S.E.C. 1034 (1984).

[133] See section III.A of this release for a discussion of the anticipated future compliance of the Bulletin Board with the requirements of section 17B(b)(2) of the Exchange Act by the effective date of the Rule. Where these external quotes are available, the broker-dealer may not use its own quotes, even if validated.

[134] A Qualifying Electronic Quotation System is defined in paragraph (c)(5) of Rule 15g–3 as "an automated quotation system that has the characteristics set forth in section 17B(b)(2) of the [Exchange] Act, or such other automated quotation system designated by the Commission" for purposes of compliance with the rule.

[135] This use of inside bid and offer quotations is consistent with the pricing provisions of Rule 3a51–1. At present, no automated quotation system satisfies all the requirements of section 17B(b)(2).

guidance to broker-dealers in complying with the rule.

The Commission also believes that the proposed 75% standard is a fair gauge of the reliability of a broker-dealer's quotes in the penny stock market. Given that there are often few trades in a penny stock, a figure lower than 75% would not accurately characterize the trading for a penny stock as "consistent." [136] The Commission agrees with the NASD that the rule would be more effective if, in determining whether it has "consistently" traded at its offer or bid price to the customer, the dealer has effected a minimum number of transactions in the security during the relevant time period. Therefore, paragraph (a)(2)(i) of the rule as adopted now requires that there must have been at least three *bona fide* interdealer transactions in the security in the five days preceding the transaction with the customer. As a logical matter, if, in fact, the dealer has effected only three transactions, all three transactions must have occurred at its offer or bid price, as the case may be.

For those principal transactions that do not have qualifying inside bid and offer quotations displayed on a Qualifying Electronic Quotation System, and also cannot be properly validated, a dealer must disclose to customers that the dealer has not consistently effected interdealer purchases or sales of the penny stock at its bid or offer price. However, the Commission does not believe this requirement to be unduly burdensome, particularly in view of the benefits it would produce in terms of customer protection. [137] The alternative would be to tell the customer nothing. The Commission believes that this result would not comply with the mandates of the Penny Stock Act, as reflected in the legislative history, which underscored the importance that investors understand the nature of quotations in the penny stock market. [138]

E. Rule 15g–4: Compensation of Brokers or Dealers

Section 15(g)(3)(A) of the Penny Stock Act requires the Commission to adopt a rule requiring broker-dealers to disclose to each customer, both prior to effecting any transaction in, and at the time of confirming any transaction with respect to, any penny stock, "the amount and description of any compensation that the broker or dealer * * * will receive or has received in connection with such transaction." [139] In enacting this provision, Congress was concerned that customers in the penny stock market have little notion of the often excessive compensation that broker-dealers obtain in penny stock transactions. [140]

1. Description of the Rule

In accordance with the Penny Stock Act, Rule 15g–4 requires disclosure of aggregate broker-dealer compensation to any customer [141] both prior to effecting any transaction in, and at the time of confirming any transaction [142] with respect to, any penny stock. [143]

Rule 15g–4 defines compensation of broker-dealers with respect to three separate types of transactions. First, the rule defines the compensation of a broker-dealer that is engaged in an agency transaction in a penny stock for a customer as the amount of any remuneration received or to be received by it from the customer. Compensation in agency transactions generally consists of a commission. The amount of remuneration to be received from the customer in agency transactions currently must be disclosed to the customer on the confirmation pursuant to Rule 10b–10(a)(7)(ii) [144] under the Exchange Act. Rule 15g–4 incorporates Rule 10b–10's general standard for agency transactions.

Second, Rule 15g–4 defines compensation of a broker-dealer, other than a dealer acting as a market maker, that executes a "riskless principal" transaction in a penny stock as the difference between the price to the customer and the contemporaneous purchase or sale that is made in connection with such transaction. A riskless principal transaction is a transaction in which a broker-dealer, after receiving (or receiving the commitment for) a buy or sell order, makes a purchase or sale of the penny stock as principal from or to another person to offset the sale or purchase as principal to or from the first person. Thus, riskless principal trades would be those trades in which there is a commitment on both the buy and the sell sides of a transaction at the time of the principal trades.

Third, Rule 15g–4 defines compensation of a dealer that executes principal transactions, other than riskless principal transactions, as the difference between the price to the customer charged by the dealer and the prevailing market price. The preamble to the rule refers broker-dealers to the standards for determining compensation in the Commission's *Alstead* [145] decision, which Congress, in its House Report on the Penny Stock Act, endorsed as the "leading case" establishing the principles for calculating mark-ups. [146]

Paragraph (d) of the rule provides an alternative standard for use by market makers in calculating compensation, once last sale reporting becomes available in a Qualifying Electronic Quotation System, as defined in paragraph (c)(5) of Rule 15g–3. At that time, solely for purposes of Rule 15g–4, a market maker may use an "active and competitive market" standard in determining prevailing market price if the aggregate number of transactions effected by such market maker in the penny stock in the five business days preceding such transaction is less than 20% of the aggregate number of all transactions in the penny stock reported on a Qualifying Electronic Quotation System. Rule 15g–4 provides that there is no presumption that a market is not "active and competitive" solely because a market maker does not meet the conditions specified therein.

2. Alstead Standard

The Commission's general principles for calculating compensation in principal trades, enunciated in its decision in *Alstead*, provide guidance in determining prevailing market price. [147] Through administrative and judicial proceedings, the Commission has maintained the long-standing position that undisclosed excessive mark-ups

[136] The Commission wishes to note that the 75% requirement, like the other requirements under the rule, is intended to apply only to transactions under Rule 15g–3.

[137] See the discussion *supra* in this section of the ABA comment that it would be unfair to require a dealer to disclose that it has not consistently effected purchases at its bid price although its sales transactions have been consistent.

[138] In adopting the bid-ask provisions of the Penny Stock Act, the House Report pointed to the fear that,

[w]hile the Committee believes that the disclosure of bid and ask quotations to customers will provide an additional source of useful information for customers to assess the relative merits of a particular investment, the Committee notes that quotations for such securities frequently are the subject of negotiation and may not accurately reflect the actual price a customer would pay or receive for the securities.

House Report, at 29.

[139] 15 U.S.C. 78*o*(g)(3)(A).

[140] See Proposing Release, 56 FR 19184.

[141] Pursuant to Rule 15g–1, a broker or dealer is not a customer.

[142] The timing and procedure of disclosure are discussed at Section III.G of this release.

[143] 15 U.S.C. 78*o*(g)(3)(A).

[144] 17 CFR 240.10b–10(a)(7)(ii).

[145] 47 S.E.C. 1034 (1984).

[146] House Report, at 30.

[147] The Proposing Release provided a summary of the standards in *Alstead* for determining prevailing market price. Proposing Release, 56 FR 19185–19186. For convenience of reference, that summary is repeated here. None of the commenters disputed the essential accuracy of the summary in the Proposing Release.

and mark-downs [148] violate the antifraud provisions of the federal securities laws,[149] and has set forth the appropriate methods for calculating dealer mark-ups. In addition, since 1943, the NASD has deemed it inconsistent with just and equitable principles of trade under its Rules of Fair Practice for a member to enter into any securities transaction with a customer at a price not reasonably related to the current price of the security.[150]

The Commission and the courts consistently have held in mark-up cases that, absent countervailing evidence, the prevailing market price is the price paid by a dealer in actual contemporaneous transactions with other dealers.[151] This standard, and a variation for certain dealer transactions, has been described most succinctly in the Commission's 1984 decision in *Alstead*.[152] The standards under *Alstead* as summarized in this release are intended to provide a framework for broker-dealers to use in calculating compensation when acting as principal in transactions in penny stocks. The Commission wishes to emphasize that this summary is not intended in any way to modify the standards of *Alstead*. Broker-dealers are encouraged to refer to that case in conjunction with this release for a statement of the Commission's standards regarding calculation of compensation.

The Commission in *Alstead* first reiterated the general contemporaneous cost standard. In one of the situations presented by the case, several market makers in an equity security were listed in the "pink sheets," and the firm in question, Alstead, Dempsey & Co., also entered quotations in regional interdealer quotation sheets. Nonetheless, the Commission held that except for the prices Alstead, Dempsey & Co. charged another dealer in two transactions, the best evidence of prevailing market price was the price paid by Alstead, Dempsey & Co. in contemporaneous transactions, in view of the unreliability of Alstead, Dempsey & Co.'s offer quote.[153]

However, in *Alstead*,[154] and in other decisions,[155] the Commission modified the contemporaneous cost standard for certain principal trades in active and competitive markets. A dealer trading in such a market, that is acting as a market maker rather than effecting a riskless principal trade, would be able to use its own contemporaneous interdealer sales price or the sales prices of other dealers, if known, in actual transactions as the basis for computing mark-ups.[156] In the absence of actual, contemporaneous interdealer sales by the market maker or other dealers, the market maker's own lowest offer quote, or the lowest offer quote of other market makers, may be used as evidence of prevailing market price in sale transactions.[157] However, in

[148] When a dealer as principal sells a security to a customer, it generally will include, as compensation, a mark-up over the prevailing market price. Similarly, when a dealer purchases a security from a customer, it will calculate a mark-down from the prevailing market price and effect the transaction at that lower price. In this release, the terms "mark-ups" and "mark-downs" will sometimes be used in lieu of "compensation" for discussion purposes, but "mark-ups" and "mark-downs" are included in the meaning of "compensation" as defined under Rule 15g-4.

[149] The Commission and the courts have stated for over 50 years that a broker-dealer, by holding itself out as a securities professional with special knowledge and ability, impliedly represents that it will deal fairly, honestly, and in accordance with industry standards with the public investor. "[A] dealer may not exploit the ignorance of his customer to extract unreasonable profits resulting from a price which bears no reasonable relation to the prevailing market price." *Duker & Duker*, 6 S.E.C. 386, 389 (1939). Specifically, a broker-dealer impliedly represents that the prices it charges bear a reasonable relation to the prevailing market price. Charging an excessive mark-up is inconsistent with that implied representation. Under this theory, the courts have found violations of Section 17(a) of the Securities Act, 15 U.S.C. § 77q(a), and Section 10(b) of the Exchange Act, 15 U.S.C. 78j(b), and Rule 10b-5 thereunder, 17 CFR 240.10b-5. *See generally Charles Hughes & Co.* v. *SEC*, 139 F.2d 434 (2d Cir.), *cert. denied*, 321 U.S. 786 (1943); *SEC* v. *Great Lakes Equities Co.*, [1990-1991] Fed. Sec. L. Rep. (CCH) ¶ 95,685, at 98,201 (E.D. Mich. September 4, 1990); *Trost & Co., Inc.*, 12 S.E.C. 531 (1942). See also Securities Exchange Act Release No. 24368 (May 5, 1987), 52 FR 15575 (principles as applied to zero coupon securities market).

[150] Interpretation of the Board of Governors, *NASD Manual* (CCH) ¶ 2154, at 2056. The NASD generally will consider mark-ups and mark-downs on equity securities greater than 5% above the prevailing market price to be unfair or unreasonable. However, the determination of the fairness of mark-ups and mark-downs must be based on a consideration of all the relevant factors, of which the percentage is only one. *Id.* at 2055, 2057. See *Gerald M. Greenberg*, 40 S.E.C. 133, 136-37 (1960).

The Commission consistently has held that undisclosed mark-ups and mark-downs of more than 10% are fraudulent in equity securities. See, *e.g., Peter J. Kisch*, 47 S.E.C. 802, 808 (1982); *Staten Securities Corp.*, 47 S.E.C. 766, 767 (1982); *Powell & Assocs.*, 47 S.E.C. 746, 748 (1982); *Charles Michael West*, 47 S.E.C. 39, 42 n.12 (1979). The Commission has applied the 10% standard in decisions involving the penny stock market as well. See *LSCO Securities, Inc.*, Securities Exchange Act Release No. 28994 (March 21, 1991), 48 SEC Doc. 767; *James E. Ryan*, 47 S.E.C. 759 (1982); *First Pittsburgh Securities Corp.*, 47 S.E.C. 299 (1980); *Costello, Russotto & Co.*, 42 S.E.C. 798 (1965); *J.A. Winston & Co.*, 42 S.E.C. 62, 69 (1964).

In addition, both the Commission and the NASD have held that compensation below the stated percentages with respect to equity securities may be excessive under certain circumstances. See *Shearson, Hammill & Co.*, 42 S.E.C. 811, 837 (1965) (Commission found markups of 5.4%, 5.7%, and 6.3% excessive and in violation of the anti-fraud laws); *Thill Securities Corp.*, 42 S.E.C. 89, 92-95 (1964) (mark-downs as low as 3.9% found to be inconsistent with NASD Rules of Fair Practice).

[151] See, *e.g., Barnett* v. *United States*, 319 F.2d 340, 344 (8th Cir. 1963). For Commission rulings, see, *e.g., First Pittsburgh Securities Corp.*, 47 S.E.C. 299, 306 (1980); *DMR Securities, Inc.*, 47 S.E.C. 180, 182 (1979); *Maryland Securities Co., Inc.*, 40 S.E.C. 443, 446 (1960); *Samuel B. Franklin & Co.*, 38 S.E.C. 908, 910 n.4, *aff'd, Samuel B. Franklin & Co.* v. *SEC*, 290 F.2d 719 (9th Cir.), *cert. denied*, 368 U.S. 889 (1961).

[152] 47 S.E.C. 1034 (1984). The Commission has applied the *Alstead* principles in decisions involving the debt securities markets. See, *e.g.*, Amicus Brief of the Securities and Exchange Commission, *Elysian Federal Savings Bank* v. *First Interregional Equity Corp.*, 713 F. Supp. 737 (D.N.J. 1989) (No. 88-3528), at 15 n.20, 20 n.27. In an interpretive statement concerning the zero-coupon securities market, the Commission stated that the best evidence of the prevailing market price would generally be the broker-dealer's contemporaneous retail purchase price, adjusted to reflect the mark-down inherent in such customer transactions. Securities Exchange Act Release No. 24368 (May 5, 1987), 52 FR 15575. Zero-coupon securities are often a proprietary product of a broker-dealer, who is usually the sole market maker in the interdealer market, if there is one.

[153] *Alstead*, at 1038. The NASD's policy in determining prevailing market price in calculating mark-ups and mark-downs is in accord with this position. The NASD's interpretation of its mark-up policy, reads, in relevant part:

Since the adoption of the "5% Policy" the Board has determined that * * * [T]he mark-up over the prevailing market price is the significant spread from the point of view of fairness of dealings with customers in principal transactions. In the absence of other bona fide evidence of the prevailing market, a member's own contemporaneous cost is the best indication of the prevailing market price of a security.

Interpretation of the Board of Governors, *NASD Manual* (CCH) ¶ 2154, at 2056.

[154] *Alstead*, at 1035-36.

[155] *See, e.g., Peter J. Kisch*, 47 S.E.C. 802, 808-809 (1982); *General Investing Corp.*, 41 S.E.C. 952, 954-55 (1964).

[156] *Alstead*, at 1036; *See also LSCO Securities, Inc.*, Securities Exchange Act Release No. 28994 (March 21, 1991), 48 SEC Doc. 767 (NASD properly computed mark-ups in certain transactions on basis of price that the firm charged another dealer); *Peter J. Kisch*, 47 S.E.C. 802, 808 (1982) (market maker's own actual contemporaneous sales to other broker-dealers should be used in computing mark-ups); *Gateway Stock and Bond, Inc.*, 43 S.E.C. 191, 194 (1966) (evidence showed that contemporaneous prices at which NASD member effected sales constitute appropriate basis for computing mark-ups). Interdealer transactions should be reasonably related to the best available quotations (*i.e.*, highest bid and lowest offer) regardless of whether such quotations are the market maker's own. Memorandum of the Division of Market Regulation to the Commission, In the Matter of Alstead, Strangis & Dempsey Inc., Administrative Proceeding File No. 3-6135 (April 8, 1983) (hereinafter referred to as "Division Memorandum"), at 21 n. 47.

[157] Quotations for NASDAQ securities that are actively traded, have narrow spreads, and have significant trading independent of the market maker in question are an example of acceptable quotations under the circumstances set forth in this release. Division Memorandum at 23.

However, the Commission cautions that quotations may be employed only in certain limited situations. The Commission stated in *Alstead*, in relevant part:

Where there is an active, independent market for a security, and the reliability of quoted offers can be tested by comparing them with actual inter-dealer transactions during the period in question, such

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order to use an offer quote, the reliability of the market maker's offer prices generally must be validated over time by comparing them with actual interdealer transactions. Although such transactions need not be contemporaneous, they would have to occur with some frequency, and consistently be effected at prices at or around the offer quotes.[158] In the absence of both actual interdealer sales and validated offer quotes, the market maker's contemporaneous cost must be employed as a basis for the mark-up computation. Contemporaneous cost is based on the market maker's purchase that is closest in time prior to the transaction.[159]

In a market dominated by a market maker to such an extent that it controls wholesale prices for a security,[160] market makers are required to apply the contemporaneous cost standard in calculating mark-ups. Where a market maker dominates the trading market for a security, it may be free to control both the quotation spreads and the trading occurring in that market. As a result, neither the market maker's offer quotations or interdealer sales may be indicative of an independent prevailing market price. Accordingly, in those situations, a market maker must use its contemporaneous purchase price in transactions with other dealers as evidence of the prevailing market price in calculating mark-ups. In the absence of actual interdealer purchases, the market maker must use its contemporaneous purchase price from retail customers, adjusted for the mark-down to such customers. This mark-down adjustment should not exceed the amount generally accepted under the NASD's mark-up rule.[161]

3. Changes From Proposed Rule

In the Proposing Release, the Commission requested comments on the proposed rule's definition of compensation[162] and the articulation in the Proposing Release of the appropriate manner of determining prevailing market price in the penny stock dealer market. The comments generally argued that the requirement in the proposed rule that dealers use the *Alstead* standards in determining prevailing market price was inappropriate, because these standards were too subjective and technically difficult to be applied effectively. Specifically, comments argued that the *Alstead* standards unfairly forced a market maker to choose between deeming a market active and competitive at the risk of a subsequent enforcement action, or using contemporaneous cost as the prevailing market price, thus disclosing compensation received by the market maker for the risk incurred in carrying an inventory position in addition to the retail component of compensation. In addition, the comments asserted that calculation of mark-ups based on contemporaneous cost would be difficult because many penny stock firms do not price their inventory on an historical basis, resulting in substantial reprogramming costs.

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quotations may provide a proper basis for computing markups. Thus, if inter-dealer sales occur with some frequency, and on the days when they occur they are consistently effected at prices at or around the quoted offers, it may properly be inferred that on other days such offers provide an accurate indication of the prevailing market.

Alstead, at 1036–37.

The Commission traditionally has believed that actual transactions are a more reliable indicator of the prevailing market price than quotations. Division Memorandum at 32. Offer quotes by OTC market makers generally are negotiable. In less active markets, market makers often purchase securities at prices higher than their bid and sell at prices lower than their offer quotes, which may even be higher than the best bid or lower than the best offer. *Id.* at 8. As the Commission further stated in *Alstead*, "quotations for obscure securities with limited interdealer trading activity may have little value as evidence of the current market." *Alstead*, at 1036. The Commission reaffirmed the lack of reliability of quotations for thinly traded securities most recently in *LSCO Securities, Inc.*, Securities Exchange Act Release No. 28994 (March 21, 1991), 48 SEC Doc. 767. See *also Gateway Stock and Bond, Inc.*, 43 S.E.C. 191, 193 (1966) ("[s]ince such offers were not generally tested in the market place by sales by the member to dealers or by other interdealer sales, they were not a reliable guide to market price."); *C.A. Benson & Co., Inc.*, 42 S.E.C. 952, 954 (1966) (firms did not sell a single share to another dealer at inside offer; thus NASD properly disregarded offering price in sheets).

[158] The Commission generally has required strong evidence that offer quotes accurately reflect prevailing market price because of the lack of reliability of quotations in the OTC market. See, *e.g.*, *Alstead*, at 1036–37; *Gateway Stock and Bond, Inc.*, 43 S.E.C. 191, 193 (1966); *Naftalin & Co., Inc.*, 41 S.E.C. 823, 826–28 (1964). Moreover, the Commission has long held that a broker-dealer in enforcement proceedings has the burden of bringing forth evidence that the use of contemporaneous cost is not appropriate for computing mark-ups or mark-downs. *See James E. Ryan*, 47 S.E.C. 759, 762 (1982) (in the absence of countervailing evidence, a dealer's contemporaneous cost is best evidence of current market price). *See also Barnett* v. *United States*, 319 F.2d 340, 344 (8th Cir. 1963); *Powell & Assocs., Inc.*, 47 S.E.C. 746, 747 (1982) (burden is on dealer to establish that contemporaneous cost is not "true market price"); *First Pittsburgh Securities Corp.*, 47 S.E.C. 299, 306 (1980) (dealer had burden to show costs did not represent mark-up); *Charles Michael West*, 47 S.E.C. 39, 41–42 (1979) (dealer has burden to establish that contemporary cost is not reliable indicator of prevailing market price).

[159] The Commission believes that same day purchases are the best indication of contemporaneous cost. However, the Commission recently has held that, absent some showing of a change in the market, contemporaneous cost may be based on interdealer purchases for a period up to five business days prior to a particular transaction. See *LSCO Securities, Inc.*, Securities Exchange Act Release No. 28994 (March 21, 1991), 48 SEC Doc. 767. See also *First Pittsburgh Securities Corp.*, 47 S.E.C. 299, 306 (1980) (contemporaneous cost not limited to same-day cost but prices paid by dealer should be "closely related in time" to its retail sales); *Advanced Research Assocs., Inc.*, 41 S.E.C. 579, 611–12 (1963) ("substantially contemporaneous" purchase prices are calculated during period with little fluctuation in purchase and sales prices). In cases of multiple purchases during the day of sale, contemporaneous cost is based on the purchase price closest in time to the sale. The average of prices during that day or any particular period of time cannot be used. *See Century Securities Co.*, 43 S.E.C. 371, 378 (1967), *aff'd sub nom. Nees* v. *SEC*, 414 F.2d 211 (9th Cir. 1969) (average cost is not appropriate evidence of market price); *Hamilton Bohner, Inc.*, Securities Exchange Act Release No. 27232 (September 9, 1989), 44 SEC Doc. 1297 (transactions over a period of time cannot be lumped together for purposes of determining fairness of mark-downs or mark-ups).

[160] In *Alstead*, the Commission found that Alstead, Dempsey & Co. dominated the market in a particular security where it had been the underwriter of that security on a "best efforts" basis and sold 95.7% of the offering to its own customers. Alstead, Dempsey & Co. became a market maker in the security, and during the period at issue, its transactions with other dealers and customers amounted to more than 297,000 shares out of a total volume of 345,000 shares, or 86% of the volume. Alstead, Dempsey & Co. effectively controlled the supply of the security since most of it was held by the registrant's customers. Only two other dealers were market makers in the stock, and their combined transactions amounted to only 7,750 shares, 2.2% of the total trading volume. The Commission consequently used Alstead, Dempsey & Co.'s contemporaneous cost of the stock in computing mark-ups. *Alstead*, at 1037.

[161] The Commission wishes to emphasize that even when disclosure of compensation is properly made under Rule 15g–4, a broker-dealer remains subject to the general antifraud provisions of the federal securities laws.

The Commission cautions that even if it fully meets the disclosure requirements of the antifraud provisions of the federal securities laws, an NASD member that charges substantial mark-ups could violate Article III, section 4 of the NASD Rules of Fair Practice, which require NASD members to "buy or sell at a price which is fair," and could violate the NASD's mark-up policy adopted under that section. Article III, section 4, *NASD Manual*, Rules of Fair Practice (CCH) ¶ 2154, at 2054. The NASD rules apply to virtually all penny stock broker-dealers. Pursuant to section 15(b)(8) of the Exchange Act, registered broker-dealers that effect securities transactions must be members of a national securities association. Currently, the NASD is the only national securities association. Only registered broker-dealers that effect securities transactions as a member of, and solely on, a national securities exchange, are not required to be NASD members. 15 U.S.C. § 78*o*(b)(8). See also Securities Exchange Act Release No. 24368 (May 5, 1987), 52 FR 15575, at 15576 n.8 (rules of just and equitable principles of trade prohibit mark-ups which are unfair in light of all other relevant circumstances, even if disclosed); *Hamilton Bohner, Inc.*, Securities Exchange Act Release No. 27232 (September 9, 1989), 44 SEC Doc. 1297 (disclosure to customers of amount of broker-dealer's profit does not in itself justify unfair profits).

[162] In the rule as proposed and in the Proposing Release, it was not clear that the amount of compensation to be disclosed is the aggregate amount of compensation to the broker-dealer in connection with a transaction. To clarify this point, the Commission has inserted the word "aggregate" before the words "amount of compensation" in paragraph (a) of Rule 15g–4.

The Commission has determined to continue to require disclosure of compensation in principal trades based on the difference between the price to the customer and the prevailing market price, as determined in accordance with the *Alstead* standards. The *Alstead* standards, developed on the basis of the Commission's long-standing precedent in matters involving excessive mark-ups, most accurately reflect the compensation received by dealers in various types of market conditions.

On the basis of the comments received and staff interviews with broker-dealers, the Commission believes that the standards enunciated in *Alstead* do not depart significantly from actual industry practice. In contrast to the *Alstead* standards, several comments suggested the use of average inventory price as the basis for calculating compensation in dominated and controlled markets. However, depending on the trend of market prices, use of average inventory pricing would result in disclosure of varying amounts of compensation. In declining markets, too little compensation would be disclosed; in rising markets, too much compensation would be disclosed.[163] Furthermore, although it appears that many broker-dealers calculate average inventory cost at the end of the day, they do not all have this information on an intra-day basis, as would be necessary to provide it to potential customers before effecting a transaction. In contrast, most traders will know their most recent acquisition cost or interdealer sales price at the time of disclosure of compensation.

In view of the stong Congressional intent that customers in the penny stock market be clearly informed of the often high compensation that broker-dealers may obtain in penny stock transactions, the Commission believes that use of the most accurate compensation standard is necessary, and that the *Alstead* standards represent the most practicable means of disclosing compensation in penny stock markets that are relatively illiquid.[164] For penny stocks that have a more developed market, broker-dealers should be able to use the safe harbor described above.

As an alternative to using *Alstead*, some comments suggested an objective standard, such as a threshold percentage of penny stock market-making, for determining when a market is "active and competitive" and "dominated and controlled." Comments referred to the quotation, last sale, and volume reporting requirements under section 17B of the Exchange Act,[165] added by the Penny Stock Act, as the source of a system for computing the percentage of total volume of a penny stock dealt in by the penny stock market maker. Another alternative suggested by comments was a cap on compensation to a broker-dealer effecting a transaction in a penny stock.[166]

After a careful review of the comment letters, the Commission agrees that a numerical standard should be available to allow a market maker to treat its market in a penny stock as "active and competitive" solely for purposes of disclosing compensation in principal transactions in the stock. Therefore, the Commission has adopted a provision permitting market makers that effect less than 20% of the transactions reported on a Qualifying Electronic Quotation System to use the "active and competitive market" standard in calculating the compensation to be disclosed under Rule 15g–4.[167] The Commission believes that allowing these market makers to determine the prevailing market price based on the "active and competitive market" standard will facilitate compliance with the rule.

As a result, therefore, once last sale reporting begins for penny stocks quoted on a Qualifying Electronic Quotation System, a market maker in a penny stock may use interdealer sales prices or properly validated offer quotations, rather than contemporaneous cost, as the prevailing market price in calculating compensation, provided that the aggregate volume of transactions effected by such market maker in the penny stock in the five business days preceding such transaction is less than 20% of the aggregate amount of all transactions in the penny stock reported on the Qualifying Electronic Quotation System. Specifically, as discussed previously, a market maker would be able to use its own contemporaneous interdealer sales price or the sales prices of other dealers, if known, in actual transactions as the basis for computing mark-ups and mark-downs if, at the time of its trade, the conditions of paragraph (d) are satisfied. In the absence of contemporaneous interdealer sales by the market maker or other dealers, the market maker's own lowest offer quote, or the lowest offer quote of other market makers, validated in accordance with the standards of *Alstead*, may be used as evidence of prevailing market price. In the absence of interdealer transactions and validated offer quotes, a market maker would have to use contemporaneous cost as the prevailing market price even though the 20% standard under paragraph (d) is satisfied.

Comments also pointed to the difficulty of determining the "riskless principal" status of a principal transaction in some instances.[168] The Proposing Release had stated that determination whether the purchase or sale of penny stock is an off-setting riskless principal transaction can only be established on a case-by-case basis.[169] Comments generally were critical of the uncertainty that such a "facts and circumstances" standard creates for dealers.[170]

The Commission agrees that dealers should have a more objective criterion for determining riskless principal status. Therefore, for purposes of Rule 15g–4, dealers could deem a transaction to be a riskless principal transaction only where commitments on both the buy and the sell sides of a transaction have been made at the time of the trade with the customer.[171] The compensation

[163] In declining markets, average cost would be more than "contemporaneous cost," the standard under *Alstead* in dominated and controlled markets, thus resulting in disclosure of less compensation than otherwise would result under *Alstead*. In rising markets, where average cost would be less than contemporaneous cost under *Alstead*, a broker-dealer would have to disclose more compensation than under *Alstead*.

[164] See Proposing Release at 56 FR 19184.

[165] 15 U.S.C. 78q–2.

[166] The ABA argued for an exemption, where investors receive a prospectus or other disclosure document prior to effecting a transaction, especially when the prospectus prominently sets forth compensation to be paid to the broker-dealer by the issuer or selling shareholder.

[167] The Commission emphasizes that it is using the Qualifying Electronic Quotation System only as a reasonable means of facilitating compliance by broker-dealers with the disclosure requirements of the Penny Stock Act. A Qualifying Electronic Quotation System may not be used to protect participants in the penny stock market otherwise engaged in fraudulent activities.

[168] Two comment letters representative of the industry criticized the inclusion of agency and riskless principal compensation in the prior trade disclosure requirement of the rule as proposed, because such information is already generally required under Rule 10b–10, and the potential for abuse in such transactions has not been demonstrated. The Commission notes that Congress, in enacting the Penny Stock Act, made no distinction in the type of compensation required to be disclosed. The Commission believes that making such an exception could enable broker-dealers more easily to engage in fraudulent activity by mischaracterizing the capacity in which they effect transactions with customers.

[169] Proposing Release, 56 FR 19185 n. 152.

[170] As an example, one comment pointed to the requirement in the proposed rule that at the time of the trade, the dealer would have to disclose the difference between the price to the customer and the counterparty price. Thus, the dealer would have to effect the other side of the transaction prior to agreeing to a trade with its customer, thereby incurring the market risk on the other side.

[171] This standard would be used in lieu of the longer one-day period, generally used at present for

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disclosure to the customer prior to the trade would be based on the price of the corresponding off-setting transaction.

In addition, the Commission understands the risk that would be imposed on market makers in making determinations of riskless principal status. Market makers already are excluded from making such a determination under Rule 10b–10.[172] Therefore, in paragraph (c)(2) of Rule 15g–4, the Commission has excluded market makers' transactions from the definition of riskless principal trades.

F. Rule 15g–5: Salesperson Compensation

As noted above, section 15(g)(3)(A)(iii) requires that the Commission adopt rules requiring brokers and dealers to disclose, prior to effecting and at the time of confirming any transaction in a penny stock, "the amount and a description of any compensation that the broker or dealer and the associated person thereof will receive or has received in connection with such transaction." High interdealer spreads and markups, which often have been found to exist in penny stock transactions, provide the potential for extraordinarily high compensation to broker-dealers and salespersons who buy and sell penny stocks. This compensation provides a strong incentive to recommend the purchase of penny stocks to customers. In enacting the provision quoted above, Congress determined that investors in penny stocks should be informed, on a transaction-by-transaction basis, of this financial incentive.[173]

Pursuant to this requirement, the Commission is adopting Rule 15g–5, which makes it unlawful for a broker-dealer to effect a nonexempt transaction in a penny stock with a customer unless the broker-dealer discloses to the customer the aggregate amount of cash compensation that certain associated persons[174] of the broker-dealer will receive, to the extent that compensation is determined at or prior to the time that the transaction is effected. Information concerning any compensation that is paid to the associated person by someone other than the broker-dealer must be separately disclosed. The rule applies to any associated person of the broker-dealer, other than a person whose functions are solely clerical or ministerial, who is a natural person and has communicated with the customer concerning the transaction at or prior to the time that the customer orders the purchase or sale of the security.

The information must be furnished orally or in writing prior to effecting the transaction, and in writing at or prior to sending the written confirmation required by Rule 10b–10. In addition, this written disclosure must disclose the existence of any contingent payments related to the transaction that are not determined at the time of the trade. The broker-dealer is required to maintain a record of the pre-trade disclosure for the period specified in 17 CFR 240.17a–4(b).

Rule 15g–5 as proposed applied to each associated person who "communicates with the customer in connection with the transaction." The Commission stated in the Proposing Release that the rule was intended to reach "those individuals who regularly solicit or recommend penny stock transactions, or otherwise communicate with customers in connection with those transactions and on whom customers are likely to rely in making investment decisions."[175] Several comments objected that the broad wording of the provision would have unintended results. In particular, these comments indicated that the rule could apply to communications by branch managers or other principals exercising ordinary supervisory responsibilities.[176] On the other hand, another comment argued that the rule should apply to "all persons who affect decision-making."[177]

As adopted, the rule applies to associated persons who "communicat[e] with the customer concerning the transaction at or prior to the customer's transaction order."[178] In addition, the rule does not apply to persons whose function is solely clerical or ministerial.[179] The Commission believes that these modifications will ensure that the rule applies to sales-related communications.[180]

The proposed rule would have permitted the broker-dealer to disclose compensation on either an aggregate or per share basis. In response to a specific request for comment, some comments favored requiring disclosure of both aggregate and per share compensation for each transaction.[181] The final rule requires disclosure only of the aggregate compensation received by the salesperson for the transaction. The Commission has determined that the form in which compensation is shown should be consistent among firms and that reflecting compensation in aggregate dollar amount will be the simplest and most easily understood form in which to present this information.[182]

The Commission noted in the Proposing Release that in some circumstances, salespersons may receive compensation directly from issuers or others.[183] As adopted, the rule requires that separate disclosure be provided with respect to any compensation that is received from sources other than the broker-dealer. This change was endorsed by several persons in response to a specific request for comment.[184] The Commission

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confirmation disclosure purposes under Rule 10b–10. For similar reasons, determination of riskless principal status would be made on the same basis for Rule 15g–3, discussed earlier in this release. See section III.D of this release.

[172] Rule 10b–10 requires broker-dealers, other than market makers, that execute riskless principal trades in equity securities to disclose the amount of any mark-up, mark-down, or similar remuneration received in the transaction. See Rule 10b–10(a)(8)(i)(A) (market-maker exclusion from markup disclosure requirement in riskless principal trades). 17 CFR 240.10b–10(a)(8)(i)(A).

[173] Proposing Release, 56 FR 19197.

[174] See the definition in Section 3(a)(18) of the Exchange Act (15 U.S.C. 78c(a)(18)).

[175] 56 FR 19188.

[176] *E.g.*, American Bar Association, Committee on Federal Regulation of Securities, Subcommittee on Broker-Dealer Matters, and Subcommittee on Partnerships ("ABA").

[177] Commonwealth of Virginia, State Corporation Commission, Division of Securities and Retail Franchising ("Virginia").

[178] This modification is drawn from a suggestion by the ABA in its comment letter.

[179] The definition of "associated person of a broker or dealer" contained in section 3(a)(18) of the Exchange Act excludes clerical or ministerial employees solely for purposes of section 15(b) of the Exchange Act, other than paragraph (6) thereof.

[180] The rule does not contain a note that was contained in the proposed rule stating that compensation would not be considered to be adequately disclosed if sales agents entered into reciprocal arrangements pursuant to which commissions were directed to persons other than customer representatives who communicated with the customer in order to evade the rule's requirements. The Commission believes that any such arrangement necessarily would be misleading and has determined that it is not necessary to attempt to identify in the rule itself particular practices that would be prohibited under existing antifraud provisions. See also section 20(b) of the Exchange Act (15 U.S.C. 78t(b)), providing that any act by a person that is unlawful under the Exchange Act or the rules adopted thereunder is likewise unlawful if conducted, directly or indirectly, through any other person.

[181] *E.g.*, North American Securities Administrators Association ("NASAA").

[182] Rule 10b–10 (17 CFR 240.10b–10), the Commission's confirmation rule, generally requires disclosure of the "amount" of "remuneration" received by a broker-dealer in a transaction for a customer.

[183] 56 FR 19188.

[184] *E.g.*, Consumer Federation of America ("CFA").

believes that the receipt of compensation from sources other than the broker-dealer presents a special inducement to recommend the security that should be disclosed to the customer.

The proposed rule would have required that firms disclose, in addition to compensation received directly in connection with the transaction, the compensation received by the salesperson from transactions in penny stocks during the prior year, if such compensation exceeded 25% of the salesperson's total sales-related compensation. This provision was intended to reflect compensation that is not paid in cash or is not paid on a transactional or per share basis and therefore to provide more accurate information to customers and prevent evasion of the Rule's requirements.[185] For example, firms may compensate their salespersons according to a "grid" system, whereby they receive a base percentage of the firm's transaction compensation that is determined at the time of each trade and also contingent payments that are tied to other factors, such as the sales revenue generated by the salesperson during each month from all or certain specified securities.

The Commission has determined to eliminate this requirement in response to a variety of strong objections. Commenters, argued, for example, that the proposed disclosure would be of limited or no value to investors, would represent significant compliance problems, or could be easily misused by salespersons to create a misleading impression.[186] Another comment noted that if the salesperson transferred to another broker-dealer, that firm would not be in a position to verify the amount of compensation paid by the previous employer.[187] Although the Commission recognizes that, depending on the compensation policies of a particular broker-dealer, the disclosure of fixed percentage compensation that is determined at the time of a trade may not completely disclose the salesperson's financial interest in that transaction, the Commission has determined that these concerns are outweighed by the practical compliance costs and difficulties that would be entailed by requiring more extensive information and by the potential that customer confusion or misuse of the information could result.

However, the Commission recognizes that "grid" or other contingent compensation arrangements may strongly motivate a salesperson's sales activities and recommendations.[188] Where the salesperson's financial interest is partly attributable to contingent payments that will be determined after the transaction, customers should be alerted to this fact in order that the disclosure required by paragraph (a)(1) will not be misleading. Accordingly, paragraph (c) of the rule requires that in such circumstances the confirmation disclosure required by the rule must indicate that contingent compensation may be paid to the salesperson in connection with the transaction and describe the basis upon which such compensation will be determined. This disclosure will serve to inform customers who wish to obtain more precise information of the need to inquire of the broker-dealer for the information. In addition, the Commission wishes to emphasize that false or misleading statements concerning compensation arrangements may violate the general antifraud provisions of the federal securities laws and that the rule does not limit or affect any affirmative obligation arising under those provisions to disclose in appropriate circumstances compensation arrangements that are not specifically covered by Rule 15g–5.[189]

G. Disclosure Procedures for Rules 15g–3, 15g–4, and 15g–5

Section 15(g)(3)(A) of the Exchange Act requires a broker-dealer effecting penny stock transactions "to disclose to each customer, prior to effecting any transaction in, and at the time of confirming any transaction with respect to any penny stock" certain information with respect to quotations, broker-dealer compensation, and associated person compensation at two different points in time.[190]

1. Description of Procedures Under the Rules

Pursuant to this provision of the Penny Stock Act, Rules 15g–3, 15g–4, and 15g–5 require a broker-dealer effecting penny stock transactions that are not exempted under Rule 15g–1 to disclose to its customers the required information at two different points in time. The initial disclosure must be given to the customer by the broker-dealer orally or in writing, prior to effecting any transaction in a penny stock. The second point at which disclosure must be made is by written confirmation to the customer. Rules 15g–3, 15g–4, and 15g–5 require broker-dealers to provide written disclosure of the information required thereunder prior to or at the time of providing customers the confirmation disclosure required under Rule 10b–10 of the Exchange Act.[191] The inclusion of the information required under Rules 15g–3, 15g–4, and 15g–5 on the Rule 10b–10 confirmation, or together with such confirmation, would comply with this requirement.

In addition, Rules 15g–3, 15g–4, and 15g–5 require the broker-dealer, at the time of making the pre-trade disclosure required under those rules to make and preserve, as part of its records, a record of such disclosure for the period specified in Rule 17a–4(b) under the Exchange Act.

2. Changes From Proposed Procedures

The timing provisions in the rules as proposed contained an exemption from the pre-trade disclosure requirement of the Penny Stock Act, provided that the broker-dealer satisfied certain conditions set forth in the exemption. Under the exemption, the broker-dealer would have been required to provide the required disclosure promptly after effecting the securities transaction, if at the time the broker-dealer provided this information, it informed the customer that the customer had the unconditional right to cancel the transaction until the end of the following business day. The broker-dealer could not attach any fee or penalty to the customer's exercise of the right of cancellation, or discourage the customer from exercising the right. In addition, the proposed rules required broker-dealers using the exemption to inform the customer in the written disclosure at the time of the confirmation that the customer had the right to cancel the transaction, that the broker-dealer has previously informed the customer of this right orally or in writing, and that the customer had not exercised this right.

The Commission requested comment on whether the proposed exemption offered protection to customers equivalent to pre-trade disclosure, and whether it would assist broker-dealers in satisfying their requirements under the rules. The Commission also requested comment whether allowing broker-dealers to provide the required information orally in the pre-trade

[185] 56 FR 19188.

[186] *E.g.*, Paulson Investment Company, Inc.

[187] RAF Financial Corporation.

[188] *See Report of the Special Study of the Securities Markets of the SEC* (1963), *reprinted in* H.R. Doc. No. 96, 88th Cong. 1st Sess. Part I 260–1.

[189] *See* Proposing Release, 56 FR 19187, n. 176 and accompanying text.

[190] 15 U.S.C. 78*o*(g)(3)(A). See Sections III.D, III.E, and III.F of this release.

[191] 17 CFR 240.10b–10. The confirmation must be provided "at or before completion" of the transaction. See 17 CFR 240.10b–10(a).

disclosure or under the exemption would provide adequate protection to customers.

Comments from both consumer organizations and the securities industry heavily criticized the provision exempting broker-dealers from the pre-trade requirement. Consumer groups believed that the exemption would greatly diminish the value of the disclosures to investors in penny stock. Comments from the securities industry focused on the procedural difficulties that would arise in complying with the requirements of the exemption.[192] Comments also were critical of providing broker-dealers with the option of oral, as opposed to written, disclosure, in either the pre-trade statement or the post-trade statement that would begin the customer's cancellation period under the exemption.[193]

The Commission agrees that the exemptive provision, with the right of cancellation, could prove to be difficult in application, and therefore has eliminated it from Rules 15g–3 through 15g–5 as adopted. The Commission had proposed the exemption principally to reduce the burden that it believed pre-trade disclosure would have imposed on firms actively engaged in the penny stock market. In reviewing written comments submitted to the Commission, and on the basis of staff discussions with broker-dealers, the Commission has concluded that pre-trade disclosure is feasible for broker-dealers because the required information is known by the firm's trading department, and thus is generally ascertainable by salespersons before a trade occurs.

Moreover, the Commission believes that the customer cancellation provision either could be the subject of broker-dealer abuse, or would be only infrequently used. On the one hand, some firms might rely on the exemption in order to avoid providing customers the required information. For example, the complexity of the exemptive provision could provide an opportunity for confusing customers. On the other hand, most broker-dealers would probably not regularly use the exemption because of the risks from the customer cancellation option.[194]

In response to the comments' generally critical view of oral, as opposed to written, pre-trade disclosure, the Commission has decided that such disclosure still may be given orally, but that the broker-dealer must make and preserve, as part of its records, a record of the facts and contents of the disclosure for the period specified in Rule 17a–4(b).[195] This would create an evidentiary record on behalf of both the broker-dealer and its customer, and, in addition, would facilitate the Commission's efforts, by inspection, to monitor compliance with the pre-trade disclosure requirement of Rules 15g–3, 15g–4, and 15g–5.

H. Rule 15g–6: Monthly Account Statements

Section 15(g)(3)(B) of the Exchange Act requires the Commission to adopt a rule to

> Require brokers and dealers to provide, to each customer whose account with the broker or dealer contains penny stocks, a monthly statement indicating the market value of the penny stocks in that account or indicating that the market value of such stock cannot be determined because of the unavailability of firm quotes * * *.

Rule 15g–6 requires a broker or dealer holding in a customer's account a penny stock, which was sold by the broker-dealer to the customer in a nonexempt transaction, to provide a monthly account statement containing specified information with respect to each penny stock held in the customer's account. The statement must be given or sent within ten days following the end of the month. Because the rule applies also to successors, any firm that acquires the business of a broker-dealer that has sold a penny stock to a customer will remain obligated to provide the monthly statements, unless the successor is separately exempted under Rule 15g–1. Rule 15g–6 and the statutory provision quoted above are intended to deter fraud and expand the availability to investors of information concerning the current market value of penny stock holdings.[196]

The account statement requirement is triggered by purchase transactions for a customer by a broker-dealer acting in either an agency or a principal capacity, unless the transaction is exempt under Rule 15g–1. Because Rule 15g–1 exempts transactions between broker-dealers, for example, the account statement requirement would not arise from solely interdealer transactions.[197]

The rule applies to firms that sell penny stocks directly to their customers, rather than to broker-dealers that provide clearing services only in connection with penny stock transactions. Introducing firms may delegate their responsibility to provide the statements required by the rule to another broker-dealer with whom they have clearing arrangements, but in each case the introducing firm remains responsible for the fulfillment of the obligation.[198]

The determination of whether a security is a penny stock for purposes of the rule is made on the last trading day of each monthly period. Paragraph (a) of the rule as adopted has been reworded to clarify this point. Paragraph (c) of the rule provides that the price of a security on a particular trading day for purposes of the rule is made at the close of business and in accordance with Rule 3a51–1(d).[199] Accordingly, a monthly statement would not be required for a security if the price of the security, based on the pricing provisions of Rule 3a51–1(d)(1), at the close of business on the last trading day of the month, is at least five dollars.[200]

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[192] For example, one comment raised the issue whether the exemptive provision required the post-trade written confirmation to state that the customer had not in fact exercised its right of cancellation due to expiration of the cancellation period, or that the customer had waived such right. If the former, the broker-dealer would have to wait until the end of the cancellation period to send the disclosure, which, if included in the confirmation pursuant to Rule 10b–10, could run afoul of the requirements of Regulation T under the Exchange Act. See 17 CFR 220.18.

Another comment argued that the right of cancellation would make compliance with Rules 15c3–1 and 15c3–3 difficult. See 17 CFR 240.15c3–1, 240.15c3–3.

[193] Comments from both consumer groups and the securities industry said that permitting oral disclosure would raise difficult evidentiary problems and that customers should have a record of the disclosure. One counsel for a broker-dealer argued that, as a legal matter, written disclosure would be required, such as notice to a customer through expedited mail delivery, but that such a procedure would be costly.

[194] The SIA stated that customers should not be given a right of cancellation because a price decline in a penny stock would induce a high rate of cancellation.

[195] 17 CFR 240.17a–4(b).

[196] Proposing Release, 56 FR 19191.

[197] The effect of the exemptions provided by Rule 15g–1 on the account statement requirement has been clarified by excluding, in paragraph (a) of Rule 15g–6, transactions that are exempt under Rule 15g–1 from the customer sale transactions that give rise to the account statement requirement.

[198] Proposing Release, 56 FR 19190.

[199] Under Rule 3a51–1(d)(1)(ii), a security is priced, other than in connection with a particular transaction, based on inside bid quotations on specified automated quotation systems or bid quotations on other interdealer quotation systems. Accordingly, if there is an inside bid quotation for the security at the close of business on the last trading day of the month, the price of the security on that day would be based on that quotation. In the absence of an inside bid quotation, the price would be based on at least three published interdealer bid quotations on the last trading day. In the absence of either an inside bid quotation or at least three interdealer bid quotations, the security would be deemed not to have a price of at least five dollars per share on that day. See section III.A.3.b.

[200] These provisions determine whether a broker-dealer must provide the market value information required by Rule 15g–6 concerning a particular security, with respect to a particular month. Although market value information is not being

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In response to a request for comment, the ABA suggested that ten days was an appropriate period within which to compile and deliver the statements. In addition, several broker-dealers that now provide account statements to some or all of their customers indicated informally to the staff that these statements are provided within this ten-day period.

Under paragraph (b) of the rule, broker-dealers are granted exemptions under two different circumstances. These exemptions exist in addition to the more comprehensive exemptions contained in Rule 15g–1.[201] First, under paragraph (b)(1), if a broker-dealer does not effect any transactions in penny stocks for or with the account of the customer for a period of six consecutive months, then following that period, the broker-dealer would not be required to provide monthly statements for each consecutive quarterly period [202] in which it effects no penny stock transactions for the customer. Instead, the broker-dealer would provide statements on a quarterly basis, within ten days following the quarter-end, for each quarterly period to which the statement relates. In other words, paragraph (b)(1) provides that if there has not been any penny stock activity in a customer's account for a period of six months, the broker-dealer thereafter may send statements on a quarterly rather than monthly basis for so long as no further penny stock transactions for the customer are effected.[203]

In addition, paragraph (b)(2) provides an exemption to account for temporary price fluctuations. It permits a broker-dealer to omit sending monthly statements with respect to a security that has a price of five dollars or more on all but five or fewer trading days of any quarterly period. In such circumstances, the broker-dealer is not required to send monthly statements with respect to that security for the following quarter and each subsequent quarter, for so long as the security continues to achieve the five dollar price threshold on the last trading day of each such quarter. Pursuant to paragraph (c), each price determination is made at the close of business on each relevant trading day in accordance with Rule 3a51–1(d), as discussed above.

This exemption may be illustrated by the following example relating to a broker-dealer holding in a customer's account a penny stock that the broker-dealer sold to the customer in a nonexempt transaction. If the security is priced at or above five dollars per share on all but five trading days of the quarter from January through March 1993, the broker-dealer is not required to send monthly statements during the April–June quarter. However, if the security is priced below five dollars per share on June 30, 1993, which is the last trading day of that quarter, the exemption will no longer be available, and the broker-dealer's obligation to provide monthly statements will resume, beginning with July 1993.

This last exemption was not contained in the proposed rule.[204] The exemption has been added largely in response to comments relating to compliance burdens associated with the movement of stocks in and out of the penny stock definition based on price within short periods of time. Where a penny stock consistently has traded above the five dollar floor over a three-month period, the Commission believes that there is less need for customers to be informed of price changes in the security on an ongoing basis and less justification for subjecting broker-dealers to the responsibility of providing monthly statements. In such circumstances, for purposes of tracking their responsibility to provide monthly statements, broker-dealers will need to monitor the price of the security on the final trading day of each succeeding quarter. Accordingly, subsequent price declines in the security may give rise to a renewed monthly statement obligation.

Under paragraph (d), each statement must disclose (i) the identity and number of shares of each penny stock for which the statement is required and (ii) the estimated market value of each of these securities, based on prescribed methods of calculation. As proposed, the rule would have required disclosure of the dates of purchase and purchase prices paid by the customer, inclusive of commissions or commission equivalents. In response to a specific request for comment, several comments supported requiring disclosure of both the amount paid, including mark-ups or commissions, as well as separate disclosure of such amounts. However, the ABA stated that this requirement would duplicate information already contained on customer confirmations [205] and that technical difficulties would arise when shares were purchased in a series of transactions or were transferred from other firms and commingled with shares purchased by the broker-dealer for the customer. As adopted, Rule 15g–6 does not require disclosure of historical purchase price information. This change will serve to simplify the information requirements without significantly compromising the information needs of customers, particularly in view of the fact that they can independently preserve this information. Moreover, the Commission understands that most firms that currently provide account statements do not provide this historical profile.

The calculation of estimated market value is predicated on the availability of one of two different types of price information. First, if there is an inside bid quotation for the security on a Qualifying Electronic Quotation System, such as the Bulletin Board, on the last trading day of the statement period, the estimated market value is equal to the highest inside bid quotation on such date, multiplied by the number of shares or units of the security in the account. Under paragraph (g)(2), in order for an "inside bid quotation" for a security to exist, at least two market makers in the security must be contemporaneously displaying, on a Qualifying Electronic Quotation System, bid and offer quotations for the security at specified prices. Where these conditions exist, the inside bid quotation is the highest bid quotation displayed on the system by a market maker. This use of inside bid quotations to calculate market value is consistent with the pricing provisions of Rule 3a51–1. [206]

Where the characterization of a security as a penny stock or the availability of an exemption from the rule's requirements depends on the pricing provisions of the rule and Rule 3a51–1, which require the existence of sufficient interdealer bid quotations, the Rules require that these quotations be *bona fide* and not made for purposes of evading compliance with the Rules.[207] Circumstances may indicate that this is not the case. For example, if a broker-dealer that otherwise would be required

required for other securities excluded or exempted from Rule 15g–6, the Commission believes that such securities should be included on the periodic statement, even absent market value disclosure. Indeed, when a firm provides periodic account statements, pursuant to the rule or otherwise, the Commission believes that it could be misleading for the firm to fail to list all of the securities that are held in the customer's account.

[201] See section III.B, *supra*.

[202] The term "quarterly period" is defined in paragraph (f)(1) of the rule as any period of three consecutive full calendar months.

[203] See the example in the Proposing Release, 56 FR at 19190.

[204] The exemption contained in paragraph (b)(1) was incorporated in the proposed rule as paragraph (a)(1). The proposed exemption from Rule 15g–6 for securities of issuers with specified net tangible assets is not necessary because these securities are now excluded from the penny stock definition.

[205] See 17 CFR 240.10b–10.

[206] See section III.A.3.

[207] See discussion at section III.A.3.b.

to send account statements relating to a security, or an affiliate, entered or published bid quotations for the security only at the end of monthly or quarterly periods, or if, on a recurring basis, its end-of-period quotations were substantially higher than the quotations of other dealers or its own quotations made at other times, the Commission believes that such circumstances would create a strong inference that the quotations were not *bona fide*.

If there is no inside bid quotation for the security on the last day of the statement period, under paragraph (d)(2)(ii), the estimated value is equal to the weighted average price per share paid by the broker-dealer furnishing the statement in all Qualifying Purchases made during the last five trading days of the statement period, if the broker-dealer has made at least ten Qualifying Purchases during that five day period. The term Qualifying Purchases is defined by paragraph (g)(4) to mean *bona fide* purchases, each of which involves at least 100 shares, by the broker-dealer for its own account.

Block purchases involving more than 1% of the outstanding shares or units are excluded from the definition of Qualifying Purchases. The proposed rule would have excluded only those block purchases exceeding 5% of the outstanding shares. The Commission has determined that the 1% exclusion will more appropriately realize the purpose of avoiding, in calculating market value, the distorting effect of transactions of inordinate size on price. [208]

If an estimated market value cannot be provided for a statement period because of the absence of an inside bid quotation or Qualifying Purchases, the statement must show that there is "no estimated market value" for the security. The absence of an estimated market value would be explained in the prescribed legend required by paragraph (e).

The proposed rule would have required the calculation of market value based on Qualifying Purchases, or if this information were not available, based on at least three Qualifying Bids during the last five days of the statement period. Qualifying Bids were defined as *bona fide*, interdealer bid quotations entered in an interdealer quotation system by market makers acting independently of each other and the broker-dealer furnishing the statement.

The Commission solicited comment on the costs that would be entailed in calculating market value and providing the account statements generally. Some comments criticized the cost of presenting a market value according to the proposed formulation, particularly in light of the fact that it would require calculations based on information that would not be available electronically and so would hinder the use of computer-generated statements. These comments suggested that this factor would cause broker-dealers to depart from current practice in providing account statements, which usually are generated by "computer feed" pursuant to an arrangement with a proprietary pricing service.

As described above, paragraph (d) permits firms to provide account statement information based on automated quotation information to the extent that it is available. [209] The Commission believes that this provision will simplify the burden and lessen the costs of complying with Rule 15g-6 and will further encourage the use of automated quotation systems for penny stocks, which may permit more effective surveillance of market activities by broker-dealers. In addition, the Penny Stock Act and section 17B of the Exchange Act [210] reflect a clear policy in favor of the development of such systems. [211]

Where these quotations are not available, the calculation of market value based on the firm's own Qualifying Purchases will permit the pricing of these securities based on information that is readily available to the broker-dealer. Further, in the absence of reliable current quotations, the prices of recent purchases by the broker-dealer furnishing the statement may provide a more reliable indicator of value to the investor than published quotation sheets, which are not binding and may reflect only indications of interest. [212]

Paragraph (e) requires that each account statement contain a legend containing prescribed language. In general, the legend states that: (i) Any estimated values contained in the statement are based on limited trades or quotes and that the customer may not be able to dispose of the securities at a price equal or near to the value indicated; (ii) the broker-dealer furnishing the statement may not refuse to accept the customer's order to sell the securities; (iii) the amount received by a customer pursuant to a sale generally will be reduced by the amount of commissions or similar charges; and (iv) if an estimated value is not provided for a particular security, such value could not be determined because of a lack of information. The legend is intended to provide perspective to investors who receive these statements and to explain the information contained in the statements.

Commenters generally supported the inclusion of a legend, although several suggested modifications. The prescribed legend has been modified in response to suggestions that it be more concise and readily understandable to unsophisticated investors. The ABA and Shearson Lehman Brothers also suggested that the legend should be permitted to be contained on the back of account statements. The Commission notes that the rule does not prescribe the placement of the legend within the account statement but does require that it be "conspicuous." In order to be considered conspicuous, the legend should contain large or otherwise distinguishable type that serves to set it apart from the other information contained in the statement. [213]

Paragraph (f) of the Rule 15g-6 requires broker-dealers furnishing account statements to maintain copies of the account statements required by paragraph (a) of the rule and to keep such records for the periods specified in 17 CFR 240.17a-4(b).

I. Proposed Rule 15g-7: Sole Market Maker Status

Proposed Rule 15g-7 would have required that, where a broker-dealer, or an affiliate, is a sole market maker with respect to a penny stock, the broker-dealer must disclose this fact to its customer and the broker-dealer or its affiliate's influence over the market for the security, prior to effecting any transaction in the security for the customer's account and in writing at or prior to the sending of the trade confirmation. In addition, proposed Rule 15g-7 also would have expressly prohibited certain representations by a market maker of a penny stock or an affiliate that effects a transaction in the security with a customer that the transaction is being effected "at the market" or a price related to the market price, unless the broker-dealer had reasonable grounds to believe that an

[208] Compare paragraph (a)(14) of Rule 10b-18 under the Exchange Act, defining the term "block" for purposes of that rule's restrictions on issuer repurchases.

[209] The NASD suggested that estimated market value be based on the inside bid quotation on the Bulletin Board or in the absence thereof, the highest of three bid quotations obtained from other dealers at the end of each month.

[210] 15 U.S.C. 78q-2.

[211] House Report 31-33.

[212] See Proposing Release, 56 FR 19191.

[213] See Proposing Release, 56 FR 19192, n. 194 and accompanying text.

independent market for the security existed. These provisions were not mandated by the Penny Stock Act but were proposed under the general rulemaking authority granted by section 15(g)(5) [214] of the Exchange Act.

Rule 15g–7 was proposed as a means of addressing the special problems associated with the control of the market for a penny stock by a single firm. In proposing the rule, the Commission recognized the nexus between the existence of a sole market maker and many of the worst abuses identified by Congress in its consideration of the Penny Stock Act.[215]

A majority of the comments that specifically addressed proposed Rule 15g–7 were generally supportive.[216] Other comments expressed concern that compliance would be difficult because firms may move in or out of market maker status with respect to particular issues on an intermittent basis and that the rule would discourage firms from becoming sole market makers for thinly-traded issues.[217]

Although the Commission continues to believe that the requirements of the proposed rule may be useful, in light of the substantial other requirements imposed by the Rules that are mandated by the Penny Stock Act, the Commission has determined to defer action on proposed Rule 15g–7 until experience has been gained with those Rules. However, the Commission wishes to emphasize that manipulative trading by sole market makers or others is violative of existing general antifraud provisions, that representations by broker-dealers to their customers relating to market price may run afoul of these provisions where no independent market exists, and that these provisions may require that a dealer acting as a sole market maker disclose its status to customers in particular circumstances.[218]

J. Rule 15c2–6

As discussed previously, Rule 15c2–6 was designed to address high pressure sales of low-priced securities to new customers. The rule requires that broker-dealers selling "designated securities" to new customers obtain financial information from the customer, make a written suitability determination concerning the customer's purchase of designated securities, obtain the customer's signature on this statement, and obtain the customer's written agreement to the trade, before the trade is effected.

Although the definition of designated security is similar in scope to the definition of penny stock in the Rules, there are certain differences in these definitions. To avoid any unnecessary burden on those broker-dealers that must comply with both sets of rules in the low-priced securities market, the Commission intends to propose amendments, as needed, to conform the definition of designated security in Rule 15c2–6 to the definition of penny stock in Rule 3a51–1.

IV. Conclusion

The Commission is adopting the Rules in order to implement provisions of the Penny Stock Act and to limit fraud in the penny stock market. The Commission solicits comment on the effectiveness of the Rules, taken together, and the effectiveness of particular Rules in preventing fraudulent sales practices, the appropriateness of the various exemptions and exclusions from the penny stock definition contained in the Rules, and the effect of the Rules on the capital-raising ability of viable small issuers. The Commission is particularly interested in the views of commenters with respect to these matters based on practical experience following the effective date.

In particular, with respect to Rule 15g–2, the Commission requests comment on whether the risk disclosure document should be required to be executed and returned by the customer, prior to the customer's first transaction in a penny stock with the broker-dealer, in order to evidence compliance with the rule. The Commission requests comment on whether this provision would further the purposes of the rule without imposing an additional unnecessary compliance burden.

Pursuant to section 4(c) of the Administrative Procedure Act ("APA"),[219] publication of Rules 3a51–1 and 15g–1 may not be made less than thirty days before their effective date, absent good cause. Certain provisions of the Penny Stock Reform Act become effective on April 15, 1992. In order to provide exemptive relief with respect to these provisions and in order to effectively implement the Commission's new barring authority under section 15(b)(6) of the Exchange Act, Rules 3a51–1 and 15g–1 shall become effective upon publication in the **Federal Register**, based on the Commission's finding of good cause.

The effective date of Rule 15g–2 is July 15, 1992. This three-month period will allow sufficient time to enable broker-dealers to prepare and distribute the risk disclosure document to branch offices. The effective date of Rules 15g–3 through 15g–6 is January 1, 1993. During discussions on the proposed rules, broker-dealers generally indicated that they would need a minimum of six months to make the necessary adjustments.

V. Effects on Competition and Regulatory Flexibility Act Considerations

Section 23(a) of the Exchange Act [220] requires that the Commission, in adopting rules under the Exchange Act, consider the anticompetitive effects of such rules, if any, and balance any anticompetitive impact against the regulatory benefits gained in terms of furthering the purposes of the Exchange Act. The Commission is of the view that the Rules will not result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act.

In addition, the Commission has prepared a Final Regulatory Flexibility Analysis ("FRFA"), pursuant to the requirements of the Regulatory Flexibility Act,[221] regarding the Rules. A copy of the FRFA may be obtained from Alexander Dill, Attorney, Office of Chief Counsel, Division of Market Regulation, Securities and Exchange Commission, 450 Fifth Street NW., Mail Stop 5–1, Washington, DC 20549, (202) 504–2418.

List of Subjects in 17 CFR Part 240

Reporting and recordkeeping requirements, Securities.

VI. Statutory Basis and Text of Amendments

In accordance with the foregoing, the Commission is amending title 17,

[214] 15 U.S.C. 78*o*(g)(5).

[215] See Proposing Release, 56 FR 19193–19194.

[216] The NASD suggested requiring disclosure, in addition to the matters covered by the proposed rule, of the risks that would result if the market maker terminated its market making activities and the general invalidity of "at the market representations" by firms that control the market.

[217] In addition, IDS Financial Services, which is a member of a large corporate family of affiliated companies, indicated that the proposed rule would pose compliance difficulties for large financial services companies with many affiliations and that procedures would need to be developed to determine if any affiliate was a sole market maker for any penny stock. Smith New Court, a market maker for securities of certain foreign issuers and American Depositary Receipts, indicated that it frequently is unaware if there are other market makers for a particular security and that, in any event, it does not exercise substantial control over the market for these securities.

[218] It is well established that broker-dealers may be liable under the antifraud provisions for failure to disclose to customers their status as market makers. *See Chasins* v. *Smith Barney & Co., Inc.*, 438 F.2d 1167 (2d Cir. 1970) and Proposing Release, 56 FR 19194, n. 202 and accompanying text.

[219] 5 U.S.C. 551 *et seq.*

[220] 15 U.S.C. 78w(a).

[221] 5 U.S.C. 604.

chapter II of the Code of Federal Regulations as follows:

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

1. The authority citation for part 240 continues to read as follows:

Authority: 15 U.S.C. 77c, 77d, 77s, 77ttt, 78c, 78d, 78i, 78j, 78l, 78m, 78n, 78o, 78p, 78s, 78w, 78x, 79q, 79t, 80a–29, 80a–37, unless otherwise noted.

2. By adding § 240.3a51–1 to read as follows:

§ 240.3a51–1 Definition of penny stock.

For purposes of section 3(a)(51) of the Act, the term "penny stock" shall mean any equity security other than a security:

(a) That is a reported security, as defined in 17 CFR 240.11Aa3–1(a) of this chapter;

except that a security that is registered on the American Stock Exchange, Inc. pursuant to the listing criteria of the Emerging Company Marketplace, but that does not otherwise satisfy the requirements of paragraphs (b), (c), or (d) of this section, shall be a penny stock for purposes of section 15(b)(6) of the Act;

(b) That is issued by an investment company registered under the Investment Company Act of 1940;

(c) That is a put or call option issued by the Options Clearing Corporation;

(d) That has a price of five dollars or more;

(1) For purposes of paragraph (d) of this section:

(i) A security has a price of five dollars or more for a particular transaction if the security is purchased or sold in that transaction at a price of five dollars or more, excluding any broker or dealer commission, commission equivalent, mark-up, or mark-down; and

(ii) Other than in connection with a particular transaction, a security has a price of five dollars or more at a given time if the inside bid quotation is five dollars or more; *provided, however,* that if there is no such inside bid quotation, a security has a price of five dollars or more at a given time if the average of three or more interdealer bid quotations at specified prices displayed at that time in an interdealer quotation system, as defined in 17 CFR 240.15c2–7(c)(1), by three or more market makers in the security, is five dollars or more.

(iii) The term "inside bid quotation" shall mean the highest bid quotation for the security displayed by a market maker in the security on an automated interdealer quotation system that has the characteristics set forth in section 17B(b)(2) of the Act, or such other automated interdealer quotation system designated by the Commission for purposes of this section, at any time in which at least two market makers are contemporaneously displaying on such system bid and offer quotations for the security at specified prices.

(2) If a security is a unit composed of one or more securities, the unit price divided by the number of shares of the unit that are not warrants, options, rights, or similar securities must be five dollars or more, as determined in accordance with paragraph (d)(1) of this section, and any share of the unit that is a warrant, option, right, or similar security, or a convertible security, must have an exercise price or conversion price of five dollars or more;

(e) That is registered, or approved for registration upon notice of issuance, on a national securities exchange that makes transaction reports available pursuant to 17 CFR 240.11Aa3–1 of this chapter, provided that:

(1) Price and volume information with respect to transactions in that security is required to be reported on a current and continuing basis and is made available to vendors of market information pursuant to the rules of the national securities exchange; and

(2) The security is purchased or sold in a transaction that is effected on or through the facilities of the national securities exchange, or that is part of a distribution of the security;

except that a security that satisfies the requirements of this paragraph, but that does not otherwise satisfy the requirements of paragraphs (a), (b), (c), or (d) of this section, shall be a penny stock for purposes of Section 15(b)(6) of the Act;

(f) That is authorized, or approved for authorization upon notice of issuance, for quotation in the National Association of Securities Dealers' Automated Quotation system (NASDAQ), provided that price and volume information with respect to transactions in that security is required to be reported on a current and continuing basis and is made available to vendors of market information pursuant to the rules of the National Association of Securities Dealers, Inc.;

except that a security that satisfies the requirements of this paragraph, but that does not otherwise satisfy the requirements of paragraphs (a), (b), (c), or (d) of this section, shall be a penny stock for purposes of section 15(b)(6) of the Act; or

(g) Whose issuer has:

(1) Net tangible assets (*i.e.*, total assets less intangible assets and liabilities) in excess of $2,000,000, if the issuer has been in continuous operation for at least three years, or $5,000,000, if the issuer has been in continuous operation for less than three years; or

(2) Average revenue of at least $6,000,000 for the last three years.

(3) For purposes of paragraph (g) of this section, net tangible assets or average revenues must be demonstrated by financial statements dated less than fifteen months prior to the date of the transaction that the broker or dealer has reviewed and has a reasonable basis for believing are accurate in relation to the date of the transaction, and:

(i) If the issuer is other than a foreign private issuer, are the most recent financial statements for the issuer that have been audited and reported on by an independent public accountant in accordance with the provisions of 17 CFR 210.2–02; or

(ii) If the issuer is a foreign private issuer, are the most recent financial statements for the issuer that have been filed with the Commission or furnished to the Commission pursuant to 17 CFR 240.12g3–2(b); *provided, however,* that if financial statements for the issuer dated less than fifteen months prior to the date of the transaction have not been filed with or furnished to the Commission, financial statements dated within fifteen months prior to the transaction shall be prepared in accordance with generally accepted accounting principles in the country of incorporation, audited in compliance with the requirements of that jurisdiction, and reported on by an accountant duly registered and in good standing in accordance with the regulations of that jurisdiction.

(4) The broker or dealer shall preserve, as part of its records, copies of the financial statements required by paragraph (g)(3) of this section for the period specified in 17 CFR 240.17a–4(b).

3. By adding § 240.15g–1 to read as follows:

§ 240.15g–1 Exemptions for certain transactions.

The following transactions shall be exempt from 17 CFR 240.15g–2, 17 CFR 240.15g–3, 17 CFR 240.15g–4, 17 CFR 240.15g–5, and 17 CFR 240.15g–6:

(a) Transactions by a broker or dealer:

(1) Whose commissions, commission equivalents, mark-ups, and mark-downs from transactions in penny stocks during each of the immediately preceding three months and during eleven or more of the preceding twelve months, or during the immediately preceding six months, did not exceed five percent of its total

commissions, commission equivalents, mark-ups, and mark-downs from transactions in securities during those months; and

(2) Who has not been a market maker in the penny stock that is the subject of the transaction in the immediately preceding twelve months.

Note: Prior to April 28, 1993, commissions, commission equivalents, mark-ups, and mark-downs from transactions in designated securities, as defined in 17 CFR 240.15c2-6(d)(2) as of April 15, 1992, may be considered to be commissions, commission equivalents, mark-ups, and mark-downs from transactions in penny stocks for purposes of paragraph (a)(1) of this section.

(b) Transactions in which the customer is an institutional accredited investor, as defined in 17 CFR 230.501(a) (1), (2), (3), (7), or (8).

(c) Transactions that meet the requirements of Regulation D (17 CFR 230.501-230.508), or transactions with an issuer not involving any public offering pursuant to section 4(2) of the Securities Act of 1933.

(d) Transactions in which the customer is the issuer, or a director, officer, general partner, or direct or indirect beneficial owner of more than five percent of any class of equity security of the issuer, of the penny stock that is the subject of the transaction.

(e) Transactions that are not recommended by the broker or dealer.

(f) Any other transaction or class of transactions or persons or class of persons that, upon prior written request or upon its own motion, the Commission conditionally or unconditionally exempts by order as consistent with the public interest and the protection of investors.

4. By adding § 240.15g-2 to read as follows:

§ 240.15g-2 Risk disclosure document relating to the penny stock market.

It shall be unlawful for a broker or dealer to effect a transaction in any penny stock for or with the account of a customer unless, prior to effecting such transaction, the broker or dealer has furnished to the customer a document containing the information set forth in Schedule 15G, 17 CFR 240.15g-100.

5. By adding section 240.15g-3 to read as follows:

§ 240.15g-3 Broker or dealer disclosure of quotations and other information relating to the penny stock market.

(a) *Requirement.* It shall be unlawful for a broker or dealer to effect a transaction in any penny stock with or for the account of a customer unless such broker or dealer discloses to such customer, within the time periods and in the manner required by paragraph (b) of this section, the following information:

(1) The inside bid quotation and the inside offer quotation for the penny stock.

(2) If paragraph (a)(1) of this section does not apply because of the absence of an inside bid quotation and an inside offer quotation:

(i) With respect to a transaction effected with or for a customer on a principal basis (other than as provided in paragraph (a)(2)(ii) of this section):

(A) The dealer shall disclose its offer price for the security:

(1) If during the previous five days the dealer has effected no fewer than three *bona fide* sales to other dealers consistently at its offer price for the security current at the time of those sales, and

(2) If the dealer reasonably believes in good faith at the time of the transaction with the customer that its offer price accurately reflects the price at which it is willing to sell one or more round lots to another dealer. For purposes of paragraph (a)(2)(i)(A) of this section, "consistently" shall constitute, at a minimum, seventy-five percent of the dealer's *bona fide* interdealer sales during the previous five-day period, and, if the dealer has effected only three *bona fide* inter-dealer sales during such period, all three of such sales.

(B) The dealer shall disclose its bid price for the security:

(1) If during the previous five days the dealer has effected no fewer than three *bona fide* purchases from other dealers consistently at its bid price for the security current at the time of those purchases, and

(2) If the dealer reasonably believes in good faith at the time of the transaction with the customer that its bid price accurately reflects the price at which it is willing to buy one or more round lots from another dealer. For purposes of paragraph (a)(2)(i)(B) of this section, "consistently" shall constitute, at a minimum, seventy-five percent of the dealer's *bona fide* interdealer purchases during the previous five-day period, and, if the dealer has effected only three *bona fide* inter-dealer purchases during such period, all three of such purchases.

(C) If the dealer's bid or offer prices to the customer do not satisfy the criteria of paragraphs (a)(2)(i)(A) or (a)(2)(i)(B) of this section, the dealer shall disclose to the customer:

(1) That it has not effected inter-dealer purchases or sales of the penny stock consistently at its bid or offer price, and

(2) The price at which it last purchased the penny stock from, or sold the penny stock to, respectively, another dealer in a *bona fide* transaction.

(ii) With respect to transactions effected by a broker or dealer with or for the account of the customer:

(A) On an agency basis or

(B) On a basis other than as a market maker in the security, where, after having received an order from the customer to purchase a penny stock, the dealer effects the purchase from another person to offset a contemporaneous sale of the penny stock to such customer, or, after having received an order from the customer to sell the penny stock, the dealer effects the sale to another person to offset a contemporaneous purchase from such customer, the broker or dealer shall disclose the best independent interdealer bid and offer prices for the penny stock that the broker or dealer obtains through reasonable diligence. A broker-dealer shall be deemed to have exercised reasonable diligence if it obtains quotations from three market makers in the security (or all known market makers if there are fewer than three).

(3) With respect to bid or offer prices and transaction prices disclosed pursuant to paragraph (a) of this section, the broker or dealer shall disclose the number of shares to which the bid and offer prices apply.

(b) *Timing.* (1) The information described in paragraph (a) of this section:

(i) Shall be provided to the customer orally or in writing prior to effecting any transaction with or for the customer for the purchase or sale of such penny stock; and

(ii) Shall be given or sent to the customer in writing, at or prior to the time that any written confirmation of the transaction is given or sent to the customer pursuant to 17 CFR 240.10b-10 of this chapter.

(2) A broker or dealer, at the time of making the disclosure pursuant to paragraph (b)(1)(i) of this section, shall make and preserve as part of its records, a record of such disclosure for the period specified in 17 CFR 240.17a-4(b).

(c) *Definitions.* For purposes of this section:

(1) The term *bid price* shall mean the price most recently communicated by the dealer to another broker or dealer at which the dealer is willing to purchase one or more round lots of the penny stock, and shall not include indications of interest.

(2) The term *offer price* shall mean the price most recently communicated by the dealer to another broker or dealer at which the dealer is willing to sell one or

more round lots of the penny stock, and shall not include indications of interest.

(3) The term *inside bid quotation* for a security shall mean the highest bid quotation for the security displayed by a market maker in the security on a Qualifying Electronic Quotation System, at any time in which at least two market makers are contemporaneously displaying on such system bid and offer quotations for the security at specified prices.

(4) The term *inside offer quotation* for a security shall mean the lowest offer quotation for the security displayed by a market maker in the security on a Qualifying Electronic Quotation System, at any time in which at least two market makers are contemporaneously displaying on such system bid and offer quotations for the security at specified prices.

(5) The term *Qualifying Electronic Quotation System* shall mean an automated interdealer quotation system that has the characteristics set forth in section 17B(b)(2) of the Act, or such other automated interdealer quotation system designated by the Commission for purposes of this section.

6. By adding § 240.15g–4 to read as follows:

§ 240.15g–4 Disclosure of compensation to brokers or dealers.

Preliminary Note: Brokers and dealers may wish to refer to Securities Exchange Act Release No. 30608 (April 20, 1992) for a discussion of the procedures for computing compensation in active and competitive markets, inactive and competitive markets, and dominated and controlled markets.

(a) *Disclosure requirement.* It shall be unlawful for any broker or dealer to effect a transaction in any penny stock for or with the account of a customer unless such broker or dealer discloses to such customer, within the time periods and in the manner required by paragraph (b) of this section, the aggregate amount of any compensation received by such broker or dealer in connection with such transaction.

(b) *Timing.* (1) The information described in paragraph (a) of this section:

(i) Shall be provided to the customer orally or in writing prior to effecting any transaction with or for the customer for the purchase or sale of such penny stock; and

(ii) Shall be given or sent to the customer in writing, at or prior to the time that any written confirmation of the transaction is given or sent to the customer pursuant to 17 CFR 240.10b–10.

(2) A broker or dealer, at the time of making the disclosure pursuant to paragraph (b)(1)(i) of this section, shall make and preserve as part of its records, a record of such disclosure for the period specified in 17 CFR 240.17a–4(b).

(c) *Definition of Compensation.* For purposes of this section, *compensation* means, with respect to a transaction in a penny stock:

(1) If a broker is acting as agent for a customer, the amount of any remuneration received or to be received by it from such customer in connection with such transaction;

(2) If, after having received a buy order from a customer, a dealer other than a market maker purchased the penny stock as principal from another person to offset a contemporaneous sale to such customer or, after having received a sell order from a customer, sold the penny stock as principal to another person to offset a contemporaneous purchase from such customer, the difference between the price to the customer and such contemporaneous purchase or sale price; or

(3) If the dealer otherwise is acting as principal for its own account, the difference between the price to the customer and the prevailing market price.

(d) *"Active and competitive"* market. For purposes of this section only, a market may be deemed to be "active and competitive" in determining the prevailing market price with respect to a transaction by a market maker in a penny stock if the aggregate number of transactions effected by such market maker in the penny stock in the five business days preceding such transaction is less than twenty percent of the aggregate number of all transactions in the penny stock reported on a Qualifying Electronic Quotation System (as defined in 17 CFR 240.15g–3(c)(5)) during such five-day period. No presumption shall arise that a market is not "active and competitive" solely by reason of a market maker not meeting the conditions specified in this paragraph.

7. By adding § 240.15g–5 to read as follows:

§ 240.15g–5 Disclosure of compensation of associated persons in connection with penny stock transactions.

(a) *General.* It shall be unlawful for a broker or dealer to effect a transaction in any penny stock for or with the account of a customer unless the broker or dealer discloses to such customer, within the time periods and in the manner required by paragraph (b) of this section, the aggregate amount of cash compensation that any associated person of the broker or dealer who is a natural person and has communicated with the customer concerning the transaction at or prior to receipt of the customer's transaction order, other than any person whose function is solely clerical or ministerial, has received or will receive from any source in connection with the transaction and that is determined at or prior to the time of the transaction, including separate disclosure, if applicable, of the source and amount of such compensation that is not paid by the broker or dealer.

(b) *Timing.* (1) The information described in paragraph (a) of this section:

(i) Shall be provided to the customer orally or in writing prior to effecting any transaction with or for the customer for the purchase or sale of such penny stock; and

(ii) Shall be given or sent to the customer in writing, at or prior to the time that any written confirmation of the transaction is given or sent to the customer pursuant to 17 CFR 240.10b–10.

(2) A broker or dealer, at the time of making the disclosure pursuant to paragraph (b)(1)(i) of this section, shall make and preserve as part of its records, a record of such disclosure for the period specified in 17 CFR 240.17a–4(b).

(c) *Contingent compensation arrangements.* Where a portion or all of the cash or other compensation that the associated person may receive in connection with the transaction may be determined and paid following the transaction based on aggregate sales volume levels or other contingencies, the written disclosure required by paragraph (b)(1)(ii) of this section shall state that fact and describe the basis upon which such compensation is determined.

8. By adding § 240.15g–6 to read as follows:

§ 240.15g–6 Account statements for penny stock customers.

(a) *Requirement.* It shall be unlawful for any broker or dealer that has effected the sale to any customer, other than in a transaction that is exempt pursuant to 17 CFR 240.15g–1, of any security that is a penny stock on the last trading day of any calendar month, or any successor of such broker or dealer, to fail to give or send to such customer a written statement containing the information described in paragraphs (c) and (d) of this section with respect to each such month in which such security is held for the customer's account with the broker or dealer, within ten days following the end of such month.

(b) *Exemptions.* A broker or dealer shall be exempted from the requirement

of paragraph (a) of this section under either of the following circumstances:

(1) If the broker or dealer does not effect any transactions in penny stocks for or with the account of the customer during a period of six consecutive calendar months, then the broker or dealer shall not be required to provide monthly statements for each quarterly period that is immediately subsequent to such six-month period and in which the broker or dealer does not effect any transaction in penny stocks for or with the account of the customer, *provided* that the broker or dealer gives or sends to the customer written statements containing the information described in paragraphs (d) and (e) of this section on a quarterly basis, within ten days following the end of each such quarterly period.

(2) If, on all but five or fewer trading days of any quarterly period, a security has a price of five dollars or more, the broker or dealer shall not be required to provide a monthly statement covering the security for subsequent quarterly periods, until the end of any such subsequent quarterly period on the last trading day of which the price of the security is less than five dollars.

(c) *Price Determinations.* For purposes of paragraphs (a) and (b) of this section, the price of a security on any trading day shall be determined at the close of business in accordance with the provisions of 17 CFR 240.3a51-1(d)(1).

(d) *Market and price information.* The statement required by paragraph (a) of this section shall contain at least the following information with respect to each penny stock covered by paragraph (a) of this section, as of the last trading day of the period to which the statement relates:

(1) The identity and number of shares or units of each such security held for the customer's account; and

(2) The estimated market value of the security, to the extent that such estimated market value can be determined in accordance with the following provisions:

(i) The highest inside bid quotation for the security on the last trading day of the period to which the statement relates, multiplied by the number of shares or units of the security held for the customer's account; or

(ii) If paragraph (d)(2)(i) of this section is not applicable because of the absence of an inside bid quotation, and if the broker or dealer furnishing the statement has effected at least ten separate Qualifying Purchases in the security during the last five trading days of the period to which the statement relates, the weighted average price per share paid by the broker or dealer in all Qualifying Purchases effected during such five-day period, multiplied by the number of shares or units of the security held for the customer's account; or

(iii) If neither of paragraphs (d)(2)(i) nor (d)(2)(ii) of this section is applicable, a statement that there is "no estimated market value" with respect to the security.

(e) *Legend.* In addition to the information required by paragraph (d) of this section, the written statement required by paragraph (a) of this section shall include a conspicuous legend that is identified with the penny stocks described in the statement and that contains the following language:

If this statement contains an estimated value, you should be aware that this value may be based on a limited number of trades or quotes. Therefore, you may not be able to sell these securities at a price equal or near to the value shown. However, the broker-dealer furnishing this statement may not refuse to accept your order to sell these securities. Also, the amount you receive from a sale generally will be reduced by the amount of any commissions or similar charges. If an estimated value is not shown for a security, a value could not be determined because of a lack of information.

(f) *Preservation of records.* Any broker or dealer subject to this section shall preserve, as part of its records, copies of the written statements required by paragraph (a) of this section and keep such records for the periods specified in 17 CFR 240.17a-4(b).

(g) *Definitions.* For purposes of this section:

(1) The term *Quarterly period* shall mean any period of three consecutive full calendar months.

(2) The *inside bid quotation* for a security shall mean the highest bid quotation for the security displayed by a market maker in the security on a Qualifying Electronic Quotation System, at any time in which at least two market makers are contemporaneously displaying on such system bid and offer quotations for the security at specified prices.

(3) The term *Qualifying Electronic Quotation System* shall mean an automated interdealer quotation system that has the characteristics set forth in section 17B(b)(2) of the Act, or such other automated interdealer quotation system designated by the Commission for purposes of this section.

(4) The term *Qualifying Purchases* shall mean *bona fide* purchases by a broker or dealer of a penny stock for its own account, each of which involves at least 100 shares, but excluding any block purchase involving more than one percent of the outstanding shares or units of the security.

9. By adding § 240.15g-100 to read as follows:

§ 240.15g-100 Schedule 15G—Information to be included in the document distributed pursuant to 17 CFR 240.15g-2.

Securities and Exchange Commission

Washington, DC 20549

Schedule 15G

Under the Securities Exchange Act of 1934

Instructions to Schedule 15G

A. The information contained in Schedule 15G ("Schedule") must be reproduced in its entirety. No language of the document may be omitted, added to, or altered in any way. No material may be given to a customer that is intended in any way to detract from, rebut, or contradict the Schedule.

B. The document entitled "Important Information on Penny Stocks" must be distributed as the first page of Schedule 15G, and on one page only. The remainder of Schedule 15G, entitled "Further Information," explains the items discussed in the first page in greater detail.

C. The disclosures made through the Schedule are in addition to any other disclosure(s) that are required to be made under the federal securities laws, including without limitation the disclosures required pursuant to the rules adopted under Sections 15(c)(1), 15(c)(2), and 15(g) of the Securities Exchange Act of 1934, 15 U.S.C. 78o(c) (1) and (2), and 15 U.S.C. 78o(g), respectively.

D. The format and typeface of the document must be reproduced as presented in the Schedule. The document may be reproduced from the Schedule by photographic copying that is clear, complete, and at least satisfies the type-size requirements set forth below for printing. In the alternative, the document may be printed and must meet the following criteria regarding typeface:

1. Words appearing in capital letters in the Schedule must be reproduced in capital letters and printed in bold-face roman type at least as large as ten-point modern type and at least two points leaded.

2. Words appearing in lower-case letters must be reproduced in lower-case roman type at least as large as ten point modern type and at least two points leaded.

3. Words that are underlined in the document must be underlined in reproduction and appear in bold-faced roman type at least as large as ten point modern type and at least two points leaded, and meet the criteria for lower-case or capital letters in paragraphs (1) and (2) above, whichever is applicable.

E. Recipients of the document must not be charged any fee for the document.

F. The content of the Schedule is as follows:

[next page]

Important Information on Penny Stocks

This statement is required by the U.S. Securities and Exchange Commission (SEC) and contains important information on penny stocks. You are urged to read it before making a purchase or sale.

Penny stocks can be very risky.

• Penny stocks are low-priced shares of small companies not traded on an exchange or quoted on NASDAQ. Prices often are not available. Investors in penny stocks often are unable to sell stock back to the dealer that sold them the stock. Thus, you may lose your investment. Be cautious of newly issued penny stock.

• Your salesperson is not an impartial advisor but is paid to sell you the stock. Do not rely only on the salesperson, but seek outside advice before you buy any stock. If you have problems with a salesperson, contact the firm's compliance officer or the regulators listed below.

Information you should get.

• *Before you buy penny stock*, federal law requires your salesperson to tell you the "*offer*" and the "*bid*" on the stock, and the "*compensation*" the salesperson and the firm receive for the trade. The firm also must mail a confirmation of these prices to you after the trade.

• You will need this price information to determine what profit, if any, you will have when you sell your stock. The offer price is the wholesale price at which the dealer is willing to sell stock to other dealers. The bid price is the wholesale price at which the dealer is willing to buy the stock from other dealers. In its trade with you, the dealer may add a retail charge to these wholesale prices as compensation (called a "markup" or "markdown").

• The difference between the bid and the offer price is the dealer's "*spread*." A spread that is large compared with the purchase price can make a resale of a stock very costly. To be profitable when you sell, the bid price of your stock must rise above the amount of this spread *and* the compensation charged by both your selling and purchasing dealers. If the dealer has no bid price, you may not be able to sell the stock after you buy it, and may lose your whole investment.

Brokers' duties and customer's rights and remedies.

• If you are a victim of fraud, you may have rights and remedies under state and federal law. You can get the disciplinary history of a salesperson or firm from the NASD at 1-800-289-9999, and additional information from your state securities official, at the North American Securities Administrators Association's central number: (202) 737-0900. You also may contact the SEC with complaints at (202) 272-7440.

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Further Information

The securities being sold to you have not been approved or disapproved by the Securities and Exchange Commission. Moreover, the Securities and Exchange Commission has not passed upon the fairness or the merits of this transaction nor upon the accuracy or adequacy of the information contained in any prospectus or any other information provided by an issuer or a broker or dealer.

Generally, penny stock is a security that:

• Is priced under five dollars;

• Is *not* traded on a national stock exchange or on NASDAQ (the NASD's automated quotation system for actively traded stocks);

• May be listed in the "pink sheets" or the NASD OTC Bulletin Board;

• Is issued by a company that has less than $5 million in net tangible assets and has been in business less than three years, by a company that has under $2 million in net tangible assets and has been in business for at least three years, or by a company that has revenues of $6 million for 3 years.

Use Caution When Investing in Penny Stocks

1. *Do not make a hurried investment decision.* High-pressure sales techniques can be a warning sign of fraud. The salesperson is not an impartial advisor, but is paid for selling stock to you. The salesperson also does not have to watch your investment for you. Thus, you should think over the offer and seek outside advice. Check to see if the information given by the salesperson differs from other information you may have. Also, it is illegal for salespersons to promise that a stock will increase in value or is risk-free, or to guarantee against loss. If you think there is a problem, ask to speak with a compliance official at the firm, and, if necessary, any of the regulators referred to in this statement.

2. *Study the company issuing the stock.* Be wary of companies that have no operating history, few assets, or no defined business purpose. These may be sham or "shell" corporations. Read the prospectus for the company carefully before you invest. Some dealers fraudulently solicit investors' money to buy stock in sham companies, artificially inflate the stock prices, then cash in their profits before public investors can sell their stock.

3. *Understand the risky nature of these stocks.* You should be aware that you may lose part or all of your investment. Because of large dealer spreads, you will not be able to sell the stock immediately back to the dealer at the same price it sold the stock to you. In some cases, the stock may fall quickly in value. New companies, whose stock is sold in an "initial public offering," often are riskier investments. Try to find out if the shares the salesperson wants to sell you are part of such an offering. Your salesperson must give you a "prospectus" in an initial public offering, but the financial condition shown in the prospectus of new companies can change very quickly.

4. *Know the brokerage firm and the salespeople with whom you are dealing.* Because of the nature of the market for penny stock, you may have to rely solely on the original brokerage firm that sold you the stock for prices and to buy the stock back from you. Ask the National Association of Securities Dealers, Inc. (NASD) or your state securities regulator, which is a member of the North American Securities Administrators Association, Inc. (NASAA), about the licensing and disciplinary record of the brokerage firm and the salesperson contacting you. The telephone numbers of the NASD and NASAA are listed on the first page of this document.

5. *Be cautious if your salesperson leaves the firm.* If the salesperson who sold you the stock leaves his or her firm, the firm may reassign your account to a new salesperson. If you have problems, ask to speak to the firm's branch office manager or a compliance officer. Although the departing salesperson may ask you to transfer your stock to his or her new firm, you do not have to do so. Get information on the new firm. Be wary of requests to sell your securities when the salesperson transfers to a new firm. Also, you have the right to get your stock certificate from your selling firm. You do not have to leave the certificate with that firm or any other firm.

Your Rights

Disclosures to you. Under penalty of federal law, your brokerage firm must tell you the following information at two different times—*before* you agree to buy or sell a penny stock, and after the trade, by *written confirmation:*

• *The bid and offer price quotes for penny stock, and the number of shares to which the quoted prices apply.* The *bid* and *offer* quotes are the wholesale prices at which dealers trade among themselves. These prices give you an idea of the market value of the stock. The dealer must tell you these price quotes if they appear on an automated quotation system approved by the SEC. If not, the dealer must use its own quotes or trade prices. You should calculate the *spread*, the difference between the bid and offer quotes, to help decide if buying the stock is a good investment.

A lack of quotes may mean that the market among dealers is not active. It thus may be difficult to resell the stock. You also should be aware that the actual price charged to you for the stock may differ from the price quoted to you for 100 shares. You should therefore determine, before you agree to a purchase, what the actual sales price (before the *markup*) will be for the exact number of shares you want to buy.

• *The brokerage firm's compensation for the trade.* A *markup* is the amount a dealer adds to the wholesale offer price of the stock and a *markdown* is the amount it subtracts from the wholesale bid price of the stock as *compensation.* A markup/markdown usually serves the same role as a broker's commission on a trade. Most of the firms in the penny stock market will be dealers, not brokers.

• *The compensation received by the brokerage firm's salesperson for the trade.* The brokerage firm must disclose to you, as a total sum, the cash compensation of your salesperson for the trade that is known at the time of the trade. The firm must describe in the written confirmation the nature of any other compensation of your salesperson that is unknown at the time of the trade.

In addition to the items listed above, your brokerage firm must send to you:

• *Monthly account statements. In general, your brokerage firm must send you a monthly statement* that gives an estimate of the value of each penny stock in your account, if there is enough information to make an estimate. If the firm has not bought or sold any penny stocks for your account for six months, it can provide these statements every three months.

Legal remedies. If penny stocks are sold to you in violation of your rights listed above, or other federal or state securities laws, you may be able to cancel your purchase and get

your money back. If the stocks are sold in a fraudulent manner, you may be able to sue the persons and firms that caused the fraud for damages. If you have signed an arbitration agreement, however, you may have to pursue your claim through arbitration. You may wish to contact an attorney. The SEC is not authorized to represent individuals in private litigation.

However, to protect yourself and other investors, you should report any violations of your brokerage firm's duties listed above and other securities laws to the SEC, the NASD, or your state securities administrator at the telephone numbers on the first page of this document. These bodies have the power to stop fraudulent and abusive activity of salespersons and firms engaged in the securities business. Or you can write to the SEC at 450 Fifth St., NW., Washington, DC 20549; the NASD at 1735 K Street, NW., Washington, DC 20006; or NASAA at 555 New Jersey Avenue, NW., Suite 750, Washington, DC 20001. NASAA will give you the telephone number of your state's securities agency. If there is any disciplinary record of a person or a firm, the NASD, NASAA, or your state securities regulator will send you this information if you ask for it.

Market Information

The market for penny stocks. Penny stocks usually are not listed on an exchange or quoted on the NASDAQ system. Instead, they are traded between dealers on the telephone in the "over-the-counter" market. The NASD's OTC Bulletin Board also will contain information on some penny stocks. At times, however, price information for these stocks is not publicly available.

Market domination. In some cases, only one or two dealers, acting as "market makers," may be buying and selling a given stock. You should first ask if a firm is acting as a *broker* (your agent) or as a dealer. A *dealer* buys stock itself to fill your order or already owns the stock. A *market maker* is a dealer who holds itself out as ready to buy and sell stock on a regular basis. If the firm is a market maker, ask how many other market makers are dealing in the stock to see if the firm (or group of firms) dominates the market. When there are only one or two market makers, there is a risk that the dealer or group of dealers may control the market in that stock and set prices that are not based on competitive forces. In recent years, some market makers have created fraudulent markets in certain penny stocks, so that stock prices rose suddenly, but collapsed just as quickly, at a loss to investors.

Mark-ups and mark-downs. The actual price that the customer pays usually includes the mark-up or mark-down. Markups and markdowns are direct profits for the firm and its salespeople, so you should be aware of such amounts to assess the overall value of the trade.

The "spread." The difference between the bid and offer price is the spread. Like a mark-up or mark-down, the spread is another source of profit for the brokerage firm and compensates the firm for the risk of owning the stock. A large spread can make a trade very expensive to an investor. For some penny stocks, the spread between the bid and offer may be a large part of the purchase price of the stock. Where the bid price is much lower than the offer price, the market value of the stock must rise substantially before the stock can be sold at a profit. Moreover, an investor may experience substantial losses if the stock must be sold immediately.

Example: If the bid is $0.04 per share and the offer is $0.10 per share, the spread (difference) is $0.06, which appears to be a small amount. But you would lose $0.06 on every share that you bought for $0.10 if you had to sell that stock immediately to the same firm. If you had invested $5,000 at the $0.10 offer price, the market maker's repurchase price, at $0.04 bid, would be only $2,000; thus you would lose $3,000, or more than half of your investment, if you decided to sell the stock. In addition, you would have to pay compensation (a "mark-up," "mark-down," or commission) to buy and sell the stock.

In addition to the amount of the spread, the price of your stock must rise enough to make up for the compensation that the dealer charged you when it first sold you the stock. Then, when you want to resell the stock, a dealer again will charge compensation, in the form of a markdown. The dealer subtracts the markdown from the price of the stock when it buys the stock from you. Thus, to make a profit, the bid price of your stock must rise above the amount of the original spread, the markup, and the markdown.

Primary offerings. Most penny stocks are sold to the public on an ongoing basis. However, dealers sometimes sell these stocks in initial public offerings. You should pay special attention to stocks of companies that have never been offered to the public before, because the market for these stocks is untested. Because the offering is on a first-time basis, there is generally no market information about the stock to help determine its value. The federal securities laws generally require broker-dealers to give investors a "prospectus," which contains information about the objectives, management, and financial condition of the issuer. In the absence of market information, investors should read the company's prospectus with special care to find out if the stocks are a good investment. However, the prospectus is only a description of the current condition of the company. The outlook of the start-up companies described in a prospectus often is very uncertain.

For more information about penny stocks, contact the Office of Filings, Information, and Consumer Services of the U.S. Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549, (202) 272-7440.

Dated: April 20, 1992.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 92-9602 Filed 4-27-92; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 230 and 240

[Release Nos. 33-6932; 34-30577; IC-18651]

RIN 3235-AD54

Blank Check Offerings

AGENCY: Securities and Exchange Commission.

ACTION: Final rules.

SUMMARY: To implement provisions of the Securities Enforcement Remedies and Penny Stock Reform Act of 1990 ("Penny Stock Reform Act"), the Commission today is adopting rules relating to registration statements filed by blank check companies offering penny stock. The rules include requirements to deposit in a special account securities issued and funds received in the offering, prohibit trading in deposited securities, disclose information regarding acquisitions by the blank check company, provide purchasers with the right to obtain a refund of deposited funds upon receipt of the information, and return deposited funds to investors if an acquisition meeting specified criteria has not been consummated within 18 months after the initial offering date.

EFFECTIVE DATES: April 28, 1992. The rules will apply to registration statements filed by blank check companies on or after April 28, 1992, as well as registration statements pending on that date.

FOR FURTHER INFORMATION CONTACT: Richard P. Konrath, Office of Disclosure Policy, Division of Corporation Finance, Securities and Exchange Commission, 450 Fifth St., NW., Washington, DC 20549, (202) 272-2589.

SUPPLEMENTARY INFORMATION: The Commission today is adopting new Rule 419 under the Securities Act of 1933 ("Securities Act"),[1] new Rule 15g-8 under the Securities Exchange Act of 1934 ("Exchange Act"),[2] and an amendment to Securities Act Rule 174.[3]

I. Executive Summary and Background

In adopting the Penny Stock Reform Act,[4] Congress recognized that fraud

[1] 15 U.S.C. 77a *et seq.* (1988).

[2] 15 U.S.C. 78a *et seq.* (1988).

[3] 17 CFR 230.174.

[4] S.647, Pub. L. 101-429.

undermines investor confidence and thereby inhibits capital formation.[5] Finding blank check offerings to be a common vehicle for fraud and manipulation in the penny stock market, Congress expressly directed the Commission to adopt rules governing registration statements filed by blank check companies offering penny stock.[6] The statute states that the special rules may include additional disclosure requirements, limitations on the use of proceeds and the distribution of securities by the issuer until the required disclosure has been made, and a right of rescission to shareholders who invested in the offering.

Pursuant to that mandate, the Commission published for comment proposed Rule 419 under the Securities Act, new Rule 15g–8 under the Exchange Act, and an amendment to Securities Act Rule 174.[7] Those proposals prescribed registration procedures for offerings by blank check companies designed to assure adequate disclosure and restrict the potential for market manipulation.[8]

The Commission today is adopting Rule 419 substantially as proposed, with changes discussed below.[9] The rule requires funds received and securities issued in an offering of penny stock by a blank check company to be placed in an escrow or trust account ("Rule 419 Account") until consummation of an acquisition(s) in which the fair value of the business(es) or the net assets that constitute a business ("net assets") acquired represents at least 80 percent of the maximum offering proceeds, including amounts received or to be received upon exercise or conversion of securities offered but excluding underwriter compensation payable to non-affiliates. The conditions include the filing of a post-effective amendment upon execution of an agreement for the acquisition of a business or assets meeting the above criteria. Upon receipt of the prospectus describing the acquisition(s), purchasers will have the opportunity to have their deposited funds (less certain withdrawals) returned. Funds will not be released from the Rule 419 Account to the registrant until the acquisition(s) meeting the specified criteria is consummated. If such an acquisition does not occur within 18 months after the effective date of the initial registration statement, funds must be returned to purchasers.

The Commission also is adopting, as proposed, new Exchange Act Rule 15g–8 and an amendment to Securities Act Rule 174. Rule 15g–8 prevents trading of securities held in the Rule 419 Account. Securities Act Rule 174 has been amended to provide that the statutory prospectus delivery period would not terminate until 90 days following the release of the blank check company's securities from the Rule 419 Account.

The principal changes from the proposed rules are as follows. First, as adopted, funds to pay certain expenses to underwriters or dealers unaffiliated with the registrant need not be deposited in the Rule 419 Account, regardless of whether the offering is on a firm commitment or contingent basis.[10] Second, the registrant may use up to 10 percent of the offering proceeds after payment of unaffiliated underwriter and dealer compensation, regardless of whether the offering is on a firm commitment or contingent basis.[11] Third, execution of an agreement for the acquisition(s) of a business(es) or assets meeting specified criteria, rather than consummation of the acquisition(s), will trigger the requirement to file a post-effective amendment under Rule 419(e). However, the release of funds from the Rule 419 Account to the registrant will not be permitted until the acquisition(s) is consummated. Fourth, the criteria that the acquisition(s) must meet have been modified to provide that the fair value of the business(es) or net assets to be acquired must represent 80 percent of the maximum offering proceeds, including funds received or to be received upon exercise or conversion of securities offered. Finally, the rule has been reorganized for clarity.

II. Discussion of the Rules

A. Scope of Rule 419

Rule 419 applies to every registration statement filed under the Securities Act relating to an offering by a blank check company.[12] The term "blank check company," restructured from the proposal,[13] means a development stage company [14] that either has no specific business plan or purpose, or has indicated that its business plan is to engage in a merger or acquisition with an unidentified company or companies; and is issuing "penny stock" as defined in Exchange Act Rule 3a51–1.[15] Rule 419 does not apply to offerings by small businesses other than blank check companies, such as investments in limited partnerships or other direct participation programs (sometimes called "blind pools") where a detailed plan of business is developed, but specific investment properties are unidentified (*e.g.*, a real estate limited partnership formed to invest in apartment buildings that have not yet been selected).[16] Likewise, start-up companies with specific business plans are not subject to Rule 419, even if operations have not commenced at the time of the offering.

In the Proposing Release, comment was solicited as to whether the definition of "blank check company" should include companies that do not have a specific percentage of offering proceeds committed to a specific business plan or purpose or an identified acquisition. While the Commission has determined not to adopt a specific percentage test as this time, it will scrutinize registered offerings for attempts to create the appearance that the registrant is not a development stage company or has a

[5] See H.R. Rep. No. 101–617; 101 Cong., 2d. Sess. at 23 (1990).

[6] See H.R. Rep. No. 101–617; 101 Cong., 2d. Sess. 10–11, 15 (1990). Of the 179 registration statement filings received and reviewed by the Commission's regional offices in calendar year 1991, approximately 36 percent involved blank check offerings (48 percent by dollar amount of the offering).

[7] Release No 33–6891 (April 17, 1991) (56 FR 19201) ("Proposing Release").

[8] Twelve letters of comment were received in response to the proposals. The comment letters and a staff summary of the letters may be inspected and copied at the Commission's Public Reference Room (File No. S7–10–91).

[9] The Penny Stock Reform Act also mandated adoption of rules regarding secondary market trading in penny stocks. Pursuant to that mandate, the Commission is adopting today, *inter alia*, a definition of the term "penny stock," which is referred to in Rule 419, as discussed in II.A. *infra*. *See* Release No. 34–30608 (April 20, 1992).

[10] Note, however, the discussion of Exchange Act Rule 15c2–4 (17 CFR 240.15c2–4) in II.B.1, *infra*.

[11] *Id.*

[12] Rule 419(a)(1). Offerings pursuant to Regulation A [17 CFR 230.251 *et seq.* (1991)] and Regulation D (17 CFR 230.501 *et seq.* (1991)) under the Securities Act are not subject to Rule 419. *But see* Securities Act Release No. 6924 [57 FR 9768] (March 23, 1992), proposing to exclude blank check offerings from Regulation A.

[13] Rule 419(a)(2) corresponds to the definition of "blank check company" in section 7(b)(3) of the Securities Act (15 U.S.C. 77g(b)(3)).

[14] A development stage company is defined in Rule 1–02(h) of Regulation S–X (17 CFR 210.1–02(h)) as a company that is devoting substantially all of its efforts to establishing a new business in which planned principal operations have not commenced, or have commenced but there has been no significant revenue therefrom.

[15] 17 CFR 240.3a51–1, adopted in Release No. 34–30608 (April 20, 1992); *see* n.9, *supra*.

[16] The Commission has recently issued an interpretative release designed to enhance the quality of information provided to investors in connection with limited partnership transactions. See Release No. 33–6900 (56 FR 28979) (June 17, 1991).

specific business plan, in an effort to avoid the application of Rule 419.

B. Rule 419 Account

1. Deposit of Funds Into an Escrow or Trust Account

Rule 419 requires the proceeds received pursuant to a blank check offering to be deposited into (i) an escrow account maintained by an insured depository institution [17] or (ii) a separate bank account established by a broker or dealer acting as trustee for persons having beneficial interests in the account.[18] If funds and securities are deposited into an escrow account maintained by an insured depository institution, that institution's deposit account records must specify that funds are held for the named purchasers of the securities in accordance with specified regulations of the Federal Deposit Insurance Corporation.[19] If funds are deposited in a separate bank account by a broker or dealer acting as a trustee, the books and records of the broker or dealer must indicate the name, address, and interest of each person for whom the account is held.[20]

As proposed, Rule 419 would have required all proceeds received in a contingent offering (*i.e.*, offering on an all-or-none or part-or-none basis) to remain in the Rule 419 Account until termination of that account. By contrast, in a firm commitment offering under the proposed rule, underwriting commissions, underwriting expenses, and dealer allowances of entities unaffiliated with the registrant were excluded from amounts required to be deposited, and up to ten percent of the proceeds to be deposited could be used by the registrant. In response to commenter concerns regarding this disparate treatment, Rule 419, as adopted, permits excluding underwriting commissions, underwriting expenses, and dealer allowances of entities unaffiliated with the registrant from amounts required to be deposited, regardless of whether the offering is on a firm commitment or contingent basis.[21] Moreover, ten percent of the net proceeds, after payment of underwriter and dealer compensation, may be released to the registrant as the proceeds are deposited in both contingent and firm commitment offerings.[22]

Unlike Rule 419, Exchange Act Rule 15c2–4 [23] does not permit the payment of underwriting commissions, underwriting expenses, and dealer allowances from proceeds required to be deposited, and prohibits the disbursal of deposited funds to the registrant in a contingent offering until the specified contingency is satisfied. With respect to a blank check offering subject to both Rule 419 and Rule 15c2–4, the requirements of Rule 15c2–4 are applicable only until the conditions of the offering governed by that Rule are met (*e.g.*, reaching the minimum in a part-or-none offering). Upon satisfaction of those conditions, Rule 419 continues to govern the use of offering proceeds.[24] This interplay between Rule 15c2–4 and Rule 419 is required to be disclosed in the initial registration statement filed by the blank check company.[25]

For example, a registrant makes a blank check offering on a best efforts, part-or-none basis, through an unaffiliated underwriter, the terms of which provide that the minimum offering is $500,000, which must be received on or before October 1, 1992, and the maximum offering is $1 million. If $500,000 is raised by the specified date, securities can continue to be sold until the stated maximum of $1 million is raised. Until the earlier of the satisfaction of the contingency or October 1, 1992, Rules 419, 15c2–4 and 10b–9 apply and no offering proceeds may be released from deposit. If on October 1, 1992, $500,000 has not been raised proceeds must be returned promptly to investors pursuant to Rules 15c2–4 and 10b–9.

If on October 1, 1992, at least $500,000 has been raised and the other obligations under Rules 15c2–4 and 10b–9 have been satisfied, such obligations cease but funds would continue to be held pursuant to Rule 419. A $50,000 underwriter commission (assuming a 10 percent commission to non-affiliates) may be paid on October 2, 1992. Ten percent of the remaining proceeds of $450,000 or $45,000, may be paid to the registrant, leaving $405,000 of offering proceeds, as well as the securities issued, in the Rule 419 Account. As further offering proceeds are received, for example, $1,000 on October 2, 1992, underwriters may be paid commissions ($100) and the registrant may receive 10 percent of the remainder ($90), leaving $810 of proceeds to be deposited in the Rule 419 Account. Thus, $405,810 of the offering proceeds is held in Rule 419 Account.

Contemplating the use of escrowed funds and bank borrowings, on December 1, 1992, the registrant files a post-effective amendment reflecting the execution of an acquisition agreement accounting for $850,000, which represents in excess of 80 percent of the maximum offering proceeds of $900,000.[26] Once the post-effective amendment is effective, the registrant must distribute the prospectus to investors. Assume that investors request refunds of $20,000 so that proceeds now in the Rule 419 Account total $385,810. The registrant would not be required pursuant to Rule 10b–9 to refund offering proceeds for failure to maintain the stated $500,000 minimum offering amount. A broker would not be deemed

[17] Rule 419(b)(1)(i)(A). Section 3(c)(2) of the Federal Deposit Insurance Act (12 U.S.C. 1813(c)(2) (1991)) defines "insured depository institution" to mean any bank or savings and loan association with deposits insured by the Federal Deposit Insurance Corporation. See also 12 U.S.C. 1813(1) (1991); and 12 U.S.C. 1821 (1991), as well as FDIC 88-47, 1988 FDIC Interp. Ltr. Lexis 47 (July 15, 1988) as to federal deposit insurance governing such accounts. If there is a material risk of non-insurance of purchasers' funds resulting from deposits in excess of the insured amounts, appropriate disclosure should be included in the prospectus. See Rule 419(c)(1).

[18] Rule 419(b)(1)(i)(B). A broker-dealer acting as trustee under Rule 419 must have net capital equal to or greater than $25,000. See Rule 15c3–1 under the Exchange Act (17 CFR 240.15c3–1).

[19] Rule 419(b)(1)(ii). Under § 330.1 of the regulations of the Federal Deposit Insurance Corporation ("FDIC") (12 CFR 330.1), the deposit account records of the insured bank are conclusive as to the existence of insurance coverage for a deposit. The relationship under which funds are deposited (*e.g.*, trustee, agent custodian or executor) must be clearly established by the deposit agreement and clearly indicated in the deposit account records to permit a claim for deposit insurance. The details of the relationship and interests of other parties in the account must be ascertainable either from the records of the bank or records of the depositor.

[20] Rule 419(b)(1)(ii).

[21] Rule 419(b)(2)(i).

[22] Rule 419(b)(2)(vi). For example, if a registrant making a $5 million blank check offering receives $100,000, amounts needed to pay the portion allocated to underwriter compensation (*e.g.*, $10,000) and ten percent of the remainder ($9,000) may be paid to the underwriter and the issuer, respectively. The remaining $81,000 would be invested in the Rule 419 Account.

[23] Under Rule 15c2–4, in a best efforts distribution of securities conducted on an "all or none" basis, or on any other basis in which payment will not be made to the issuer until some further event or contingency occurs, a broker-dealer participant is obligated either to segregate funds received in a separate bank account, as agent or trustee, or to deposit promptly such funds with a bank pursuant to a written escrow agreement, pending the occurrence of the contingency. Under Rule 15c3–1(b) (17 CFR 240.15c3–1(b)), broker-dealers that do not carry customer accounts or that are affiliated with the issuer must deposit offering funds in an escrow account established at a bank.

[24] An explanatory note has been added to Rule 419(b).

[25] Rule 419(c). See also the discussion of Rule 10b–9 [17 CFR 240.10b–] in II.C *infra*.

[26] Although the maximum was $1 million, for purposes of the 80 percent calculation, Rule 419(e)(1) permits the exclusion of underwriter and dealer compensation payable to non-affiliates, which would amount to $100,000 in this example.

to be in violation of Rule 15c2–4 for having received commissions after October 1, since the minimum offering terms were met as initially specified.

Funds deposited in a Rule 419 Account and interest or dividends thereon must be held for the sole benefit of the purchasers [27] in one of the following accounts: (1) An obligation that constitutes a "deposit" as that term is defined in section 3(1) of the Federal Deposit Insurance Act; [28] (2) securities of any open-end investment company registered under the Investment Company Act of 1940 that holds itself out as a money market fund [29]; or (3) securities that are direct obligations of, or obligations guaranteed as to principal or interest by, the United States.[30] Commenters expressed concern regarding the potential fluctuation in value of government securities and the ability to liquidate those securities within time periods specified in Rule 419. Although the Rule continues to permit investments in government securities, registrants are cautioned that such an investment would be inappropriate unless the instrument could be readily sold or otherwise disposed of for cash within the constraints of Rule 419 without any dissipation of offering proceeds invested.[31]

The proposing release solicited comment regarding the registration of the Rule 419 Account as an investment company under the Investment Company Act. Although a Rule 419 Account may be an investment company under the Investment Company Act of 1940,[32] in light of the purposes served by the regulatory requirement to establish such an account, the limited nature of the investments, and the limited duration of the account, such an account will neither be required to register as an investment company nor regulated as an investment company as long as it meets the requirements of Rule 419.

2. Deposit of Securities Into and Escrow or Trust Account

Requirements regarding the deposit of securities into the Rule 419 Account are adopted as proposed. Accordingly, all securities sold in an offering by a blank check company, as well as securities issued in connection with the offering to underwriters, promoters or others as compensation or otherwise, must be placed in the Rule 419 Account and subject to the following conditions.[33] The securities must be issued in the name of the purchaser, remain in that form, and held for the sole benefit of purchasers, who will have the voting rights, if any, provided by applicable state law.[34] In addition, deposited securities may not be transferred or disposed of, except by will or the laws of descent and distribution, pursuant to a qualified domestic relations order as defined, or to permit the exercise or conversion of derivative securities held in the escrow or trust account.[35]

Frequently, securities sold by blank check companies are issued in units consisting of common stock and warrants or convertible securities relating to the common stock (*e.g.*, a unit consisting of one share of common stock and two common stock warrants or other derivative securities relating to the common stock). While permitting the exercise or conversion of securities held in a Rule 419 Account, Rule 419 requires the deposit of securities received upon exercise or conversion, as well as any cash or other consideration paid in connection with exercise or conversion.[36]

3. Prohibition on Trading in Deposited Securities

Exchange Act Rule 15g–8 is adopted as proposed. Following the initial sale of the blank check company's securities, new Exchange Act Rule 15g–8 prohibits any sale of deposited securities or interests in these securities until the securities are released from the Rule 419 Account. Therefore, contracts of sale to be satisfied by delivery of the deposited security, such as contracts for sale on a when, as, and if-issued basis, and sale of derivative securities settled by delivery of the security, such as a physically-settled option on the security, are prohibited by Rule 15g–8 while the securities are in the Rule 419 Account. In addition, Rule 15g–8 prohibits the sale of other interests based on the deposited security, whether or not physical delivery is required.

C. Release of Funds and Securities From the Rule 419 Account

To effect release of funds and securities from the Rule 419 Account, the following conditions must be met. First, the registrant must execute an agreement for the acquisition(s) of a business(es) or assets for which the fair value of the business(es) or net assets to be acquired represents at least 80 percent of the maximum offering proceeds, including funds received or to be received upon exercise or conversion of securities offered, but excluding underwriting commissions, underwriting expenses and dealer allowances payable to non-affiliates.[37] Second, upon execution of that agreement, the registrant must file a post-effective amendment with the Commission providing the disclosure required by Rule 419(e).[38] Third, no later than five business days after the effective date of that post-effective amendment, the registrant must send each purchaser a copy of the prospectus contained in the post-effective amendment and any amendment or supplement thereto.[39]

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[27] Rule 419(b)(2)(iii). Rule 419(a)(3) defines "purchaser" as any person acquiring securities in the offering, for cash or otherwise, including promoters or others receiving securities as compensation in connection with the offering.

[28] 12 U.S.C. 1813(1) (1991).

[29] Money market funds are open-end management investment companies registered under the Investment Company Act of 1940 ("Investment Company Act") 15 U.S.C. 80a-1 *et seq.*) that invest in short-term debt instruments. There are currently 710 money market funds with over $538 billion in assets. See IBC/Donoghue's Money Fund Report (Feb. 8, 1991). Most money market funds maintain a stable price of $1.00 per share. The stable $1.00 per share prices has encouraged investors to view money market funds as an alternative to bank deposit and checking accounts, even though money market funds lack federal deposit insurance. See Investment Company Act Release No. 18005 (February 20, 1991) (56 FR 8113), at n. 2 and 3.

[30] Rule 419 (b)(2)(iv).

[31] A cautionary note has been set forth in the Rule. The staff of the Division of Market Regulation has articulated this approach with respect to investments in government securities in the context of Exchange Act Rule 15c2–4. See NASD Notice to Members 84–7 (January 30, 1984)

[32] *See Prudential Insurance Co.* v. *S.E.C.*, 326 F.2d 383 (3d Cir. 1964), *cert. denied*, 377 U.S. 953 (1964) (a "fund" need not be a recognizable business entity in order to be an issuer for purposes of the investment Company Act).

[33] Rule 419(b)(3)(i). Securities issued for consideration other than cash (*e.g.*, as a dividend) also must be deposited, as well as securities issued in respect of already deposited securities (*e.g.*, securities issued as a result of a stock split or dividend or upon exercise or conversion).

[34] Rule 419(b)(3)(ii). Upon request by the Commission or the staff, the registrant would be required to furnish as supplemental information the names and addresses of purchasers of securities in the Rule 419 Account. Rule 419(b)(5).

[35] Rule 419(b)(3) (ii) and (iii).

[36] Rule 419(b)(3)(iii).

[37] Rule 419(e)(1). The acquisition must constitute the business or a line of business of the registrant. Two or more acquisitions that together meet the criteria specified in Rule 419(e) will be treated in the same manner as a single such acquisition.

[38] *Id.* If at any time during the offering a significant acquisition between the registrant and another company is probable, a post-effective amendment to the registration statement would be required pursuant to Rule 419(d), adopted as proposed (proposed Rule 419(c)). See also Item 512(a)(1)(ii) of Regulation S–K (17 CFR 229.512(a)(1)(ii)); and Securities Act Release No. 6383 (March 16, 1982)(47 FR 11380), text accompanying n. 80, 47 FR at 11396.

[39] Rule 419(e)(2)(i).

Fourth, the registrant must give each purchaser no fewer than 20 business days and no more than 45 business days from the effective date of the post-effective amendment to notify the registrant that he or she elects to remain an investor.[40] If purchaser notification is not received by the registrant within the prescribed time, the purchaser's deposit must be refunded. Fifth, the registrant must consummate the acquisition(s) meeting the criteria set forth above.[41] Funds may not be released until the consummation of the acquisition and the receipt by the escrow agent or trustee of a signed representation from the registrant that the above conditions have been met.[42]

There are two circumstances under which funds will be returned to the purchaser and securities returned to the registrant. First, as noted above, if upon receipt of the prospectus purchasers do not confirm an intent to invest within the prescribed time, their funds must be returned to them.[43] Second, if the conditions noted above are not met within 18 months after the effective date of the registrant's initial registration statement, deposited funds must be returned to purchasers.[44]

The following requirements have been changed from the proposals. Execution of an agreement for the acquisition(s) of a business(es) or assets meeting specified criteria, rather than consummation of the acquisition as proposed, will trigger filing of the post-effective amendment required in Rule 419(e). Difficulties noted by commenters in consummating an acquisition without knowledge of the amount of confirmed investments prompted this change. However, the acquisition(s) must be consummated before funds may be released from the Rule 419 Account to the registrant. The criteria for the acquisition(s), as adopted, are that the fair value of the business(es) or net assets to be acquired must represent at least 80 percent of the maximum offering proceeds, including funds received or to be received upon exercise or conversion of securities offered, but excluding underwriter and dealer compensation payable to non-affiliates.[45]

In the Proposing Release, the Commission inquired as to the conditions which would be most appropriate for the release of funds and securities from a Rule 419 Account. Following a review of the public comments and its experience with blank check offerings, the Commission has determined that the protection of investors is best served through a test that is measured against the maximum proceeds sought to be acquired in the offering. Thus under the Rule as adopted, funds in a Rule 419 Account may be disbursed to the registrant only when an amount equivalent to at least 80 percent of the maximum offering proceeds sought, including those obtainable, currently or in the future, through the exercise or conversion of any security offered, has been applied to an acquisition(s) of a business or assets that constitute the business or a line of business of the registrant.[46]

Further, with respect to stock acquisitions, the proposing release provided that the resulting entity must have net tangible assets equal to the greater of 80 percent of proceeds or $100,000. Since there is not a sufficient basis to distinguish a cash acquisition and a stock acquisition in a blank check offering, the Rule adopted today provides for one acquisition standard applicable to both. The net tangible asset standard proposed is, accordingly, unnecessary. An acquisition for either cash or securities will be able to meet the standard if the fair value [47] of the business(es) or net assets to be acquired represents at least 80 percent of the maximum offering proceeds.

In certain contingent offerings, Rule 419 provisions relating to the release of funds and Exchange Act Rule 10b–9 obligations will apply. Rule 10b–9 prohibits as a "manipulative or deceptive device or contrivance" under section 10(b) of the Exchange Act [48] any representation that a security is being offered on an "all or none" or "part or none" basis, unless prompt refunds are made to purchasers if the represented number of securities is not sold at the specified price within the specified time and the total amount due the seller is not received by the seller by the specified date.

Just as with Rule 15c2–4, for blank check offerings subject to both Rule 419 and Rule 10b–9, the requirements of Rule 10b–9 apply until the conditions of the offering governed by that Rule are met (*e.g.*, reaching the minimum in a part-or-none offering). Upon satisfaction of Rule 10b–9, the provisions of Rule 419 will continue to govern.[49] Proposed Rule 419(b)(2)(i)(B) would have required a refund of proceeds if as a result of purchaser refund the terms of the offering governed by Rule 10b–9 were no longer met, but that requirement has not been adopted. The initial registration statement filed by the blank check company making a contingent offering subject to Rule 10b–9 must disclose that the provisions of that Rule apply only until the conditions subject to that Rule are met, but after satisfaction of such conditions an investor is not guaranteed a return of proceeds even if, as a result of investor refund requests under Rule 419, the Rule 10b–9 conditions would no longer be met.[50] The risks to the investor resulting from the issuer receiving less than the minimum specified proceeds as a result of later refunds under Rule 419 must be clearly disclosed.

D. Disclosure Obligations Under Rule 419

Disclosure obligations under Rule 419 are adopted substantially as proposed.

1. Disclosure in Initial Prospectus

The initial prospectus for a Rule 419 offering must describe the obligation of the registrant to deposit funds and securities in the Rule 419 Account, the restrictions on trading in securities held in the Account, and the conditions for release of deposited funds and securities.[51] The effect of these requirements on purchasers and the registrant's right to receive funds also must be described.[52] In addition, a copy of the executed escrow or trust agreement must be filed as an exhibit to the initial registration statement and

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[40] Rule 419(e)(2)(ii).

[41] Rule 419(e)(2)(iii).

[42] Rule 419(e)(3)(i).

[43] Rule 419(e)(2)(ii).

[44] Rule 419(e)(2)(iv).

[45] As proposed, the criteria would have been that the post-effective amendment be filed upon consummation of an acquisition that would account for at least 80 percent of the deposited proceeds or, where securities were issued in the acquisition, the resulting entity would have net tangible assets equivalent to the greater of 80 percent of the deposited proceeds or $100,000.

[46] Rule 419(e)(1).

[47] A note has been added to the Rule providing that in a cash acquisition, fair value is presumed to be equal to the cash paid. When non-cash consideration, such as securities, is used, fair value is to be determined by an accepted standard, such as bona fide sales, forecasts of expected cash flows, independent appraisals, etc. The valuation must be reasonable at the time made.

[48] 15 U.S.C. 78j(b).

[49] An explanatory note has been added to Rule 419(e). *See* the example of the interaction of Rules 419, 15c2–4 and 10b–9 in II.B.1. *supra*.

[50] Rule 419(c). Of course, the registrant may choose to provide that funds be returned to investors if a minimum is not met because of Rule 419 refunds.

[51] Rule 419(c).

[52] If purchasers receive interest or dividends on deposited funds, the prospectus must set forth the tax effect on the purchaser, including the possibility of having to pay taxes on such income and being required to file an amended tax return to receive a tax refund if ultimately the interest or dividend income is released to the blank check company.

contain provisions specified in Rule 419.[53]

2. Disclosure in Post-Effective Amendment Describing an Acquisition Agreement

A post-effective amendment filed pursuant to Rule 419(e) describing an acquisition agreement must contain the following information. First, all information specified by the applicable registration statement form and Industry Guides would be included.[54] That information would include financial statements of the issuer and company to be acquired, as well as pro forma financial information reflecting the acquisition, as specified by the form and applicable rules and regulations. Second, the gross amount of offering proceeds received pursuant to the offering would be required to be disclosed, specifying the amounts paid for underwriter commissions, underwriting expenses and dealer allowances, amounts disbursed to the registrant, and amounts remaining in the escrow or trust account.[55] Third, the registrant would be required to detail the use of funds received, if any, under the terms of the escrow or trust agreement.[56] This disclosure would delineate amounts paid to officers, directors, promoters and others and the reasons for such payments, *e.g.*, compensation, reimbursement of expenses, purchase of assets from such individuals, etc. Finally, the post-effective amendment prospectus, like the initial prospectus, must describe the terms of the offering, including the conditions imposed on the offering by Rule 419.[57] If funds and securities are released from the Rule 419 Account, this prospectus would be supplemented by sticker to indicate the amount of funds and securities released and the date of release.[58]

3. Financial Statements

Rule 419(f), adopted substantially as proposed, requires the blank check company to furnish security holders with audited financial statements for the first full fiscal year of operations following the date an acquisition is consummated pursuant to the Rule,[59] accompanied by a management's discussion and analysis of such information,[60] no later than 90 days after the end of the fiscal year.[61] That information also would be filed with the Commission under cover of Form 8–K.[62] Pursuant to this provision, investors in the blank check company would have the financial statements and related information for at least a full accounting period following commencement of operations of the company. If at the end of its first full fiscal year of operations the blank check company was filing reports pursuant to Section 13(a) or 15(d) of the Exchange Act,[63] this requirement would not be applicable, since it would duplicate those reporting requirements.

E. Amendment to Rule 174

The amendment to Rule 174 is adopted as proposed. Rule 174 under the Securities Act prescribes prospectus delivery requirements with respect to transactions subject to section 4(3) of the Securities Act.[64] Under section 4(3), transactions by dealers are exempt from the prospectus delivery and other requirements of section 5 of the Securities Act unless those transactions are within 40 days of the date securities were first offered to the public, or 90 days if the securities have not been sold previously pursuant to an earlier effective registration statement. New paragraph (g) of Rule 174 provides that with respect to offerings subject to Rule 419, the prospectus delivery period would not terminate until 90 days after the release of funds and securities from the Rule 419 Account.

III. Cost-Benefit Analysis

No specific empirical data was submitted in response to the Commission's invitation to provide information on the costs and benefits of the proposed rules. A review of the information provided by blank check issuers in their registration statements reveals that their cost of initial registration are typically the lowest of any issuers. The purpose for the legislative directive to develop these rules was to counteract many abusive practices which were found in markets for blank check securities. While additional costs to registrants and broker-dealers may result from the new rules, such costs are expected to be outweighed by the increased protection of investors in blank check offerings.

IV. Availability of Final Regulatory Flexibility Analysis

The Commission has prepared a Final Regulatory Flexibility Analysis, pursuant to the requirements of the Regulatory Flexibility Act,[65] regarding the new rules. The Final Regulatory Flexibility Analysis indicates that the rules could impose some additional costs on small broker-dealers and small issuers. The rules are designed to minimize these costs to the greatest extent possible consistent with the provisions of the Penny Stock Reform Act. A copy of the Final Regulatory Flexibility Analysis may be obtained from Richard P. Konrath, Attorney-Advisor, Office of Disclosure Policy, Division of Corporation Finance, Securities and Exchange Commission, 450 Fifth Street, NW., Mail Stop 3–12, Washington, D.C. 20549, (202) 272–2589.

V. Effective Date

The rules relating to blank check offerings are effective upon publication in the **Federal Register**. The Commission finds that there is good cause to dispense with the 30 day delay between publication and effectiveness normally required by the Administrative Procedure Act.[66] Focusing on demonstrated abuses in connection with blank check offerings that cause harm to investors, Congress in the Penny Stock Reform Act directed the Commission to enact a special regulatory scheme that goes beyond disclosure to provide substantive protections to investors. Congressional concern was focused on the recent history of blank check offerings as an area rife with fraud and manipulation, particularly in view of the lack of information at the commencement of a blank check offering about the manner in which proceeds will be used, and the potential for dissipation of those proceeds. These abuses were found to be inadequately addressed by the current regulatory

[53] Rule 419(b)(4). Those provisions include Rule 419(b)(2) (deposit and investment of proceeds), Rule 419(b)(3) (deposit of securities), and Rule 419(e)(3) (conditions for the release of deposited securities and funds).

[54] Rule 419(e)(1)(i). This information also would be included in a post-effective amendment filed pursuant to Rule 419(d) reflecting a probable significant acquisition.

[55] Rule 419(e)(1)(ii).

[56] *Id.* In addition, Form SR under the Securities Act (17 CFR 239.61) requires first-time registrants to file with the Commission at specified intervals reports describing its use of offering proceeds. See Securities Act Rule 463 (17 CFR 230.463).

[57] Rule 419(e)(1)(iii).

[58] Rule 419(e)(4).

[59] The registrant, as currently required, would be subject to section 15(d) of the Exchange Act for at least the first fiscal year following the effective date of the initial registration statement.

[60] Item 303(a) of Regulation S–K (17 CFR 229.303(a)).

[61] Rule 419(f). Proposed Rule 419(d)(6) required financial statements for the first full fiscal year of operations following the effective date of the post-effective amendment; a specific reference to the date of a consummated acquisition was not contained because under the proposals, unlike the adopted rules, consummation was a condition to filing the post-effective amendment.

[62] 17 CFR 249.308, Item 7.

[63] 15 U.S.C. 78m(a) (1988); 15 U.S.C. 78o(d) (1988).

[64] 15 U.S.C. 77d(3) (1988).

[65] 5 U.S.C. 603 (1988).

[66] 5 U.S.C. 553(d)(3).

scheme, and in need of immediate attention in order to prevent investors from further harm. These abuses and the protections that would be imposed by the new rules have been publicized in the Proposing Release and elsewhere.

None of the Commission's current provisions provide for the escrowing of proceeds and securities, the restriction on trading in escrowed securities or the right of investors to obtain the return of invested funds upon receipt of complete information about an acquisition. Congress believed that such protections were needed for the protection of investors in blank check offerings. Delay in the effectiveness of these rules very likely could frustrate the legislative intent behind the provisions by permitting anticipatory filings in order to avoid compliance. Similarly, a substantial number of registration statements by blank check issuers are currently on file with the Commission. Very few provide restrictions on the use of proceeds or other protections similar to those required by the new rules, which are needed in order to prevent the abuse that was the subject of Congressional concern. The Commission finds that it is in the interest of investors that these rules apply to both pending as well as future filings by blank check issuers.

VI. Statutory Basis

New Rule 419 and the amendment to Rule 174 are being adopted by the Commission pursuant to sections 3,[67] 4,[68] 5,[69] 7,[70] and 19 [71] of the Securities Act. New Rule 15g–8 is being adopted pursuant to sections 3,[72] 9,[73] 10,[74] 15,[75] and 23 [76] of the Exchange Act.

List of Subjects in 17 CFR Parts 230 and 240

Advertising, Brokers, Confidential business information, fraud, Investment companies, Reporting and recordkeeping requirements, and Securities.

VII. Text of New Rules

In accordance with the foregoing, title 17, chapter II of the Code of Federal Regulations is amended as follows:

[67] 15 U.S.C. 77c (1988).
[68] 15 U.S.C. 77d (1988).
[69] 15 U.S.C. 77e (1988).
[70] 15 U.S.C. 77g (1988).
[71] 15 U.S.C. 77s (1988).
[72] 15 U.S.C. 78c (1988).
[73] 15 U.S.C. 78i (1988).
[74] 15 U.S.C. 78j (1988).
[75] 15 U.S.C. 78o (1988).
[76] 15 U.S.C. 78w (1988).

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

1. The authority citation for part 230 is revised to read as follows:

Authority: 15 U.S.C. 77b, 77c, 77d, 77e, 77f, 77g, 77h, 77j, 77s, 77sss, 78c, 78*l*, 78m 78n, 78o, 78w, 79t, and 80a–37, as amended, unless otherwise noted.

2. By amending § 230.174 by adding paragraph (g) to read as follows:

§ 230.174 Delivery of prospectus by dealers; exemptions under section 4(3) of the Act.

* * * * *

(g) If the registration statement relates to an offering of securities of a "blank check company," as defined in Rule 419 under the Act (17 CFR 230.419), the statutory period for prospectus delivery specified in section 4(3) of the Act shall not terminate until 90 days after the date funds and securities are released from the escrow or trust account pursuant to Rule 419 under the Act.

3. By adding § 230.419 under the undesignated center heading "General Requirements" to read as follows:

§ 230.419 Offerings by blank check companies.

(a) *Scope of the rule and definitions.* (1) The provisions of this section shall apply to every registration statement filed under the Act relating to an offering by a blank check company.

(2) For purposes of this section, the term "blank check company" shall mean a company that:

(i) Is a development stage company that has no specific business plan or purpose or has indicated that its business plan is to engage in a merger or acquisition with an unidentified company or companies, or other entity or person; and

(ii) Is issuing "penny stock," as defined in Rule 3a51–1 (17 CFR 240.3a51–1) under the Securities Exchange Act of 1934 ("Exchange Act").

(3) For purposes of this section, the term "purchaser" shall mean any person acquiring securities directly or indirectly in the offering, for cash or otherwise, including promoters or others receiving securities as compensation in connection with the offering.

(b) *Deposit of securities and proceeds in escrow or trust account*—(1) General. (i) Except as otherwise provided in this section or prohibited by other applicable law, all securities issued in connection with an offering by a blank check company and the gross proceeds from the offering shall be deposited promptly into:

(A) An escrow account maintained by an "insured depository institution," as that term is defined in section 3(c)(2) of the Federal Deposit Insurance Act (12 U.S.C. 1813(C)(2)); or

(B) A separate bank account established by a broker or dealer registered under the Exchange Act maintaining net capital equal to or exceeding $25,000 (as calculated pursuant to Exchange Act Rule 15c3–1 (17 CFR 240.15c3–1), in which the broker or dealer acts as trustee for persons having the beneficial interests in the account.

(ii) If funds and securities are deposited into an escrow account maintained by an insured depository institution, the deposit account records of the insured depository institution must provide that funds in the escrow account are held for the benefit of the purchasers named and identified in accordance with 12 CFR 330.1 of the regulations of the Federal Deposit Insurance Corporation, and the records of the escrow agent, maintained in good faith and in the regular course of business, must show the name and interest of each party to the account. If funds and securities are deposited in a separate bank account established by a broker or dealer acting as a trustee, the books and records of the broker-dealer must indicate the name, address, and interest of each person for whom the account is held.

(2) Deposit and investment of proceeds. (i) All offering proceeds, after deduction of cash paid for underwriting commissions, underwriting expenses and dealer allowances, and amounts permitted to be released to the registrant pursuant to paragraph (b)(2)(vi) of this section, shall be deposited promptly into the escrow or trust account; *provided, however,* that no deduction may be made for underwriting commissions, underwriting expenses or dealer allowances payable to an affiliate of the registrant.

(ii) Deposited proceeds shall be in the form of checks, drafts, or money orders payable to the order of the escrow agent or trustee.

(iii) Deposited proceeds and interest or dividends thereon, if any, shall be held for the sole benefit of the purchasers of the securities.

(iv) Deposited proceeds shall be invested in one of the following:

(A) An obligation that constitutes a "deposit," as that term is defined in section 3(*l*) of the Federal Deposit Insurance Act (12 U.S.C. 1813 (*l*));

(B) Securities of any open-end investment company registered under the Investment Company Act of 1940 (15

U.S.C. 80a–1 et seq.) that holds itself out as a money market fund meeting the conditions of paragraphs (c)(2), (c)(3), and (c)(4) of 17 CFR 270.2a–7 (Rule 2a–7) under the Investment Company Act; or

(C) Securities that are direct obligations of, or obligations guaranteed as to principal or interest by, the United States.

Note to § 230.419(b)(2)(iv): Issuers are cautioned that investments in government securities are inappropriate unless such securities can be readily sold or otherwise disposed of for cash at the time required without any dissipation of offering proceeds invested.

(v) Interest or dividends earned on the funds, if any, shall be held in the escrow or trust account until the funds are released in accordance with the provisions of this section. If funds held in the escrow or trust account are released to a purchaser of the securities, the purchasers shall receive interest or dividends earned, if any, on such funds up to the date of release. If funds held in the escrow or trust account are released to the registrant, interest or dividends earned on such funds up to the date of release may be released to the registrant.

(vi) The registrant may receive up to 10 percent of the proceeds remaining after payment of underwriting commissions, underwriting expenses and dealer allowances permitted by paragraph (b)(2)(i) of this section, exclusive of interest or dividends, as those proceeds are deposited into the escrow or trust account.

(3) Deposit of securities. (i) All securities issued in connection with the offering, whether or not for cash consideration, and any other securities issued with respect to such securities, including securities issued with respect to stock splits, stock dividends, or similar rights, shall be deposited directly into the escrow or trust account promptly upon issuance. The identity of the purchaser of the securities shall be included on the stock certificates or other documents evidencing such securities. See also 17 CFR 240.15g–8 regarding restrictions on sales of, or offers to sell, securities deposited in the escrow or trust account.

(ii) Securities held in the escrow or trust account are to remain as issued and deposited and shall be held for the sole benefit of the purchasers, who shall have voting rights, if any, with respect to securities held in their names, as provided by applicable state law. No transfer or other disposition of securities held in the escrow or trust account or any interest related to such securities shall be permitted other than by will or the laws of descent and distribution, or pursuant to a qualified domestic relations order as defined by the Internal Revenue Code of 1986 as amended (26 U.S.C. 1 *et seq.*), or Title 1 of the Employee Retirement Income Security Act (29 U.S.C. 1001 *et seq.*), or the rules thereunder.

(iii) Warrants, convertible securities or other derivative securities relating to securities held in the escrow or trust account may be exercised or converted in accordance with their terms; *provided, however*, that securities received upon exercise or conversion, together with any cash or other consideration paid in connection with the exercise or conversion, are promptly deposited into the escrow or trust account.

(4) Escrow or trust agreement. A copy of the executed escrow or trust agreement shall be filed as an exhibit to the registration statement and shall contain the provisions of paragraphs (b)(2), (b)(3), and (e)(3) of this section.

(5) Request for supplemental information. Upon request by the Commission or the staff, the registrant shall furnish as supplemental information the names and addresses of persons for whom securities are held in the escrow or trust account.

Note to § 230.419(b): With respect to a blank check offering subject to both Rule 419 and Exchange Act Rule 15c2–4 (17 CFR 240.15c2–4, the requirements of Rule 15c2–4 are applicable only until the conditions of the offering governed by that Rule are met (*e.g.*, reaching the minimum in a "part-or-none" offering). When those conditions are satisfied, Rule 419 continues to govern the use of offering proceeds.

(c) *Disclosure of offering terms.* The initial registration statement shall disclose the specific terms of the offering, including, but not limited to:

(1) The terms and provisions of the escrow or trust agreement and the effect thereof upon the registrant's right to receive funds and the effect of the escrow or trust agreement upon the purchaser's funds and securities required to be deposited into the escrow or trust account, including, if applicable, any material risk of non-insurance of purchasers' funds resulting from deposits in excess of the insured amounts; and

(2) The obligation of the registrant to provide, and the right of the purchaser to receive, information regarding an acquisition, including the requirement that pursuant to this section, purchasers confirm in writing their investment in the registrant's securities as specified in paragraph (e) of this section.

(d) *Probable acquisition post-effective amendment requirement.* If, during any period in which offers or sales are being made, a significant acquisition becomes probable, the registrant shall file promptly a post-effective amendment disclosing the information specified by the applicable registration statement form and Industry Guides, including financial statements of the registrant and the company to be acquired as well as pro forma financial information required by the form and applicable rules and regulations. Where warrants, rights or other derivative securities issued in the initial offering are exercisable, there is a continuous offering of the underlying security.

(e) *Release of deposited and funds securities*— (1) Post-effective amendment for acquisition agreement. Upon execution of an agreement(s) for the acquisition(s) of a business(es) or assets that will constitute the business (or a line of business) of the registrant and for which the fair value of the business(es) or net assets to be acquired represents at least 80 percent of the maximum offering proceeds, including proceeds received or to be received upon the exercise or conversion of any securities offered, but excluding amounts payable to non-affiliates for underwriting commissions, underwriting expenses, and dealer allowances, the registrant shall file a post-effective amendment that:

(i) Discloses the information specified by the applicable registration statement form and Industry Guides, including financial statements of the registrant and the company acquired or to be acquired and pro forma financial information required by the form and applicable rules and regulations;

(ii) Discloses the results of the initial offering, including but not limited to:

(A) The gross offering proceeds received to date, specifying the amounts paid for underwriter commissions, underwriting expenses and dealer allowances, amounts disbursed to the registrant, and amounts remaining in the escrow or trust account; and

(B) The specific amount, use and application of funds disbursed to the registrant to date, including, but not limited to, the amounts paid to officers, directors, promoters, controlling shareholders or affiliates, either directly or indirectly, specifying the amounts and purposes of such payments; and

(iii) Discloses the terms of the offering as described pursuant to paragraph (e)(2) of this section.

(2) Terms of the offering. The terms of the offering must provide, and the registrant must satisfy, the following conditions.

(i) Within five business days after the effective date of the post-effective

amendment(s), the registrant shall send by first class mail or other equally prompt means, to each purchaser of securities held in escrow or trust, a copy of the prospectus contained in the post-effective amendment and any amendment or supplement thereto;

(ii) Each purchaser shall have no fewer than 20 business days and no more than 45 business days from the effective date of the post-effective amendment to notify the registrant in writing that the purchaser elects to remain an investor. If the registrant has not received such written notification by the 45th business day following the effective date of the post-effective amendment, funds and interest or dividends, if any, held in the escrow or trust account shall be sent by first class mail or other equally prompt means to the purchaser within five business days;

(iii) The acquisition(s) meeting the criteria set forth in paragraph (e)(1) of this section will be consummated if a sufficient number of purchasers confirm their investments; and

(iv) If a consummated acquisition(s) meeting the requirements of this section has not occurred by a date 18 months after the effective date of the initial registration statement, funds held in the escrow or trust account shall be returned by first class mail or equally prompt means to the purchaser within five business days following that date.

(3) Conditions for release of deposited securities and funds. Funds held in the escrow or trust account may be released to the registrant and securities may be delivered to the purchaser or other registered holder identified on the deposited securities only at the same time as or after:

(i) The escrow agent or trustee has received a signed representation from the registrant, together with other evidence acceptable to the escrow agent or trustee, that the requirements of paragraphs (e)(1) and (e)(2) of this section have been met; and

(ii) Consummation of an acquisition(s) meeting the requirements of paragraph (e)(2)(iii) of this section.

(4) Prospectus supplement. If funds and securities are released from the escrow or trust account to the registrant pursuant to this paragraph, the prospectus shall be supplemented to indicate the amount of funds and securities released and the date of release.

Notes to § 230.419(e)

Note 1. With respect to a blank check offering subject to both Rule 419 and Exchange Act Rule 10b-9 (17 CFR 240.10b-9), the requirements of Rule 10b-9 are applicable only until the conditions of the offering governed by that Rule are met (*e.g.*, reaching the minimum in a "part-or-none" offering). When those conditions are satisfied, Rule 419 continues to govern the use of offering proceeds.

Note 2. If the business(es) or assets are acquired for cash, the fair value shall be presumed to be equal to the cash paid. If all or part of the consideration paid consists of securities or other non-cash consideration, the fair value shall be determined by an accepted standard, such as bona fide sales of the assets or similar assets made within a reasonable time, forecasts of expected cash flows, independent appraisals, etc. Such valuation must be reasonable at the time made.

(f) *Financial statements.* The registrant shall:

(1) Furnish to security holders audited financial statements for the first full fiscal year of operations following consummation of an acquisition pursuant to paragraph (e) of this section, together with the information required by Item 303(a) of Regulation S-K (17 CFR 229.303(a)), no later than 90 days after the end of such fiscal year; and

(2) File the financial statements and additional information with the Commission under cover of Form 8-K (17 CFR 249.308); *provided, however,* that such financial statements and related information need not be filed separately if the registrant is filing reports pursuant to Section 13(a) or 15(d) of the Exchange Act.

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

4. The authority citation for part 240 continues to read as follows:

Authority: 15 U.S.C. 77c, 77d, 77s, 77ttt, 78c, 78d, 78i, 78j, 78*l*, 78m, 78n, 78o, 78p, 78s, 78w, 78x, 79q, 79t, 80a-29, 80a-37, unless otherwise noted:

5. By adding § 240.15g-8 to read as follows:

§ 240.15g-8 Sales of Escrowed Securities of Blank Check Companies

As a means reasonably designed to prevent fraudulent, deceptive, or manipulative acts or practices, it shall be unlawful for any person to sell or offer to sell any security that is deposited and held in an escrow or trust account pursuant to Rule 419 under the Securities Act of 1933 (17 CFR 230.419), or any interest in or related to such security, other than pursuant to a qualified domestic relations order as defined by the Internal Revenue Code of 1986, as amended (26 U.S.C. 1 *et seq.*), or Title I of the Employee Retirement Income Security Act (29 U.S.C. 1001 *et seq.*), or the rules thereunder.

Dated: April 13, 1992.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 92-9605 Filed 4-27-92; 8:45 am]

BILLING CODE 8010-01-M

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 240

[Release No. 34-30610; File No. S7-10-92]

RIN 3235-AF46

Sales Practice Requirements for Certain Low-Priced Securities

AGENCY: Securities and Exchange Commission.

ACTION: Proposed amendments.

SUMMARY: The Securities and Exchange Commission ("Commission") is publishing for comment amendments to Rule 15c2-6 under the Securities Exchange Act of 1934 ("Exchange Act"). In general, unless a transactional exemption is available, Rule 15c2-6 makes it unlawful for a broker or dealer to sell or effect the purchase of a "designated security" unless the broker or dealer has specifically approved the purchaser's account for transactions in designated securities and has received the purchaser's written agreement to the transaction. The proposed amendments would conform the definition of "designated security" in Rule 15c2-6 with the definition of "penny stock" in Rule 3a51-1 and, except for the established customer exemption, would replace the transactional exemptions under the rule with the transactional exemptions under Rule 15g-1. With a few exceptions, the changes to Rule 15c2-6 would be primarily structural and would not significantly alter the scope of the rule. In addition, the Commission is proposing to amend Schedule 15G under the Exchange Act to include a brief description of a broker-dealer's obligations to its customers under Rule 15c2-6.

DATES: Comments should be received on or before May 28, 1992.

ADDRESSES: Comments should be submitted in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549. All comment letters should refer to File No. S7-10-92. All comments received will be available for public inspection and copying in the Commission's Public Reference Room, 450 5th Street, NW., Washington, DC 20549.

FOR FURTHER INFORMATION CONTACT: Robert L. D. Colby, Chief Counsel, John M. Ramsay, Branch Chief, Belinda Blaine, Attorney, or Alexander Dill, Attorney, at (202) 504-2418, Office of Chief Counsel, Division of Market Regulation, Securities and Exchange Commission, 450 Fifth Street NW., Mail Stop 5-1, Washington, DC 20549.

SUPPLEMENTARY INFORMATION:

I. Introduction

In August, 1989, the Commission adopted Rule 15c2-6 to address sales practice abuses involving speculative low-priced securities that are traded in the over-the-counter ("OTC") market.[1] Rule 15c2-6, which became effective on January 1, 1990, generally prohibits a broker-dealer from selling to or effecting the purchase of a "designated security" by any person, unless the broker-dealer has approved the purchaser's account for transactions in designated securities and received the purchaser's written agreement to the transaction. In approving an account for transactions in designated securities, a broker-dealer must obtain sufficient information from the purchaser to make an appropriate suitability determination, provide the purchaser with a written statement setting forth the basis of the determination, and obtain a signed copy of the suitability statement from the purchaser.

Subsequent to the adoption of Rule 15c2-6, Congress passed the Securities Enforcement Remedies and Penny Stock Reform Act of 1990 ("Penny Stock Act").[2] Section 503 of the Penny Stock Act added a new Section 3(a)(51) to the Exchange Act, which generally defines the term "penny stock" to include equity securities other than securities that are traded on a national exchange or automated quotation system meeting criteria established by the Commission, issued by a registered investment company, or otherwise excluded or exempted by the Commission based on price, net tangible assets, or other relevant criteria. Section 3(a)(51) also gives the Commission broad discretion to exclude or exempt other securities from the definition of penny stock. The Penny Stock Act also added section 15(g) to the Exchange Act, which, in addition to mandating specific disclosures by broker-dealers in penny stock transactions, gives the Commission the authority to exempt persons or transactions from the disclosure requirements of section 15(g).

Pursuant to this authority, on April 10, 1992, the Commission adopted Rule 3a51-1, which defines the term "penny stock" to exclude certain additional categories of equity securities, and Rule 15g-1, which exempts certain transactions from the disclosure requirements of Rules 15g-2 through 15g-6 under the Exchange Act ("Penny Stock Rules").[3] In proposing the Penny Stock Rules, the Commission had particularly solicited comment on whether Rule 15c2-6 should be amended to be consistent with those rules.[4] In response, several comments urged the Commission to adopt conforming changes to Rule 15c2-6.[5] These comments argued that making the scope of Rule 15c2-6 consistent with the Penny Stock Rules would eliminate costs and facilitate compliance with all of the rules.

In light of these comments, the Commission is proposing to amend Rule 15c2-6 to replace the definition of designated security with Rule 3a51-1's definition of penny stock and, except for the established customer exemption, to substitute the list of exempt transactions in paragraph (c) of Rule 15c2-6 with the exempt transactions under Rule 15g-1. With certain exceptions, discussed below, the changes to Rule 15c2-6 would be primarily structural, and would not alter the scope or the substantive requirements of the rule. The Commission believes that Rule 15c2-6 and the Penny Stock Rules should be consistent because these rules are aimed at curbing abuses in essentially the same market—namely, the market for low-priced securities that principally are quoted in the "pink sheets" published by the National Daily Quotation Service and in the NASD's OTC Bulletin Board. Moreover, making the scope of Rule 15c2-6 consistent with the Penny Stock Rules will simplify compliance with all of the rules. Broker-dealers will be able to avoid having to implement separate but overlapping compliance procedures to monitor

[1] Securities Exchange Act Release No. 27160 (August 22, 1989), 54 FR 35468.

[2] Public Law 101-429, 104 Stat. 931 (1990). The Penny Stock Act was designed to address the lack of public information about penny stocks, as well as problems of recidivism among promoters and other persons involved in penny stock offerings.

[3] Securities Exchange Act Release No. 30608 (April 20, 1992) ("Adopting Release"). The Penny Stock Rules require broker-dealers, prior to effecting a transaction in a penny stock, to disclose to their customers certain information concerning the transaction and the penny stock market in general. Specifically, Rule 15g-2 requires broker-dealers to provide a risk disclosure document, as set forth in Schedule 15G; Rule 15g-3 requires disclosure of bid and ask quotations; Rules 15g-4 and 15g-5 require disclosure of any broker-dealer and associated person compensation in connection with the transaction; and Rule 15g-6 requires the provision of monthly account statements.

[4] The Penny Stock Rules were proposed for public comment in Securities Exchange Act Release No. 29093 (April 17, 1991), 56 FR 19165 ("Proposing Release").

[5] American Bar Association; Dean Witter Reynolds, Inc.; Merrill Lynch, Pierce, Fenner & Smith Inc.; National Association of Securities Dealers, Inc. ("NASD"); Shearson Lehman Brothers, Inc.; and the Security Traders Association.

trades in both designated securities and penny stocks. Finally, to make the risk disclosure document required by Rule 15g-2 more comprehensive, the Commission is proposing amendments to Schedule 15G under the Exchange Act to add to the existing discussion of broker-dealer obligations under the Penny Stock Rules a brief description of broker-dealer responsibilities under Rule 15c2-6.

II. Description of the Proposed Amendments

A. Amendments to Rule 15c2-6

1. Definition

Rule 15c2-6's requirement that broker-dealers document their suitability determination and obtain written customer consent to the transaction only applies to non-exempt transactions in "designated securities." The proposed amendments would replace the definition of "designated security" and this term, which is used solely for purposes of Rule 15c2-6, with Rule 3a51-1's definition of "penny stock."

Although the definition of penny stock is substantially the same as the current definition of designated security, it differs in a few respects.[6] The proposed amendments would eliminate these differences. Specifically, Rule 3a51-1(g) also contains an exclusion for securities whose issuer has demonstrated net tangible assets of $2 million, but limits the exclusion to issuers that have been in operation for at least three years. Issuers that have been in operation for less than three years must have at least $5 million in net tangible assets to be excluded from the definition of penny stock. In the Adopting Release, the Commission stated that the rule imposes a separate higher standard for start-up companies in order to prevent the types of abusive activities that have occurred both prior to and since the adoption of Rule 15c2-6 in August of 1989.[7] In addition to the exclusion based on issuer net tangible assets, however, Rule 3a51-1 includes an alternative exclusion for any penny stock that is issued by an issuer with average revenues of $6 million for the past three years.[8] This new alternative exclusion was added to mitigate the impact of the Penny Stock Rules on small operating issuers that are unable to meet the net tangible assets level, but that nevertheless have significant revenues.

Like Rule 15c2-6, Rule 3a51-1 contains an exclusion for any security that is authorized, or approved for authorization upon notice of issuance, for quotation on NASDAQ. The exclusion in Rule 3a51-1, however, is subject to the condition that price and volume information with respect to transactions in that security is required to be reported on a current and continuing basis and is made available to vendors of market information pursuant to the rules of the NASD. The Commission recently approved an NASD proposal to require members to report to the NASD the execution price and the number of shares of each trade in NASDAQ securities within 90 seconds after execution.[9] Once the NASD implements real-time last sale trade reporting pursuant to the terms of this proposal, all NASDAQ securities will be excluded from the definition of penny stock under paragraph (f) of Rule 3a51-1.

Similarly, Rule 3a51-1 provides an exclusion in paragraph (e) for any security that is registered, or approved for registration upon notice of issuance, on a national securities exchange,[10] provided that current price and volume information with respect to transactions in that security is required to be reported and is made available to vendors pursuant to the rules of the national securities exchange. Unlike the analogous exclusion in 15c2-6, this exclusion is only available for regional exchange-listed securities that actually are purchased or sold through the facilities of the exchange or in a distribution.[11] As the Commission noted in the Adopting Release, the exclusion is limited in order to address Congress' concern that securities that would otherwise be considered penny stocks because they are primarily traded in the non-NASDAQ OTC market nevertheless may be able to avoid Commission rules designed to protect investors by becoming listed on an exchange.[12]

Finally, several technical changes would be made to Rule 15c2-6 to make the rule consistent with the Penny Stock Rules. For example, the exemption for transactions in securities priced at five dollars or more, described below, would instead become an exclusion from the definition. Thus, securities with a price of five dollars or more would continue to be outside of the coverage of Rule 15c2-6,[13] as would securities issued by a registered investment company and put and call options issued by the OCC.

2. Exemptions

Paragraph (c) of Rule 15c2-6 provides an exemption for any transaction: (1) In which the price of the security is five dollars or more (including any share of any unit that has an independent exercise or conversion price); (2) in which the purchaser is an accredited investor, as defined in Regulation D under the Securities Act of 1933 ("Securities Act"); (3) that is not recommended by the broker-dealer; and (4) by a broker-dealer who is not acting as a market maker in the designated security and whose commissions, commission equivalents, and mark-ups from transactions in designated securities during a specified period, did not exceed five percent of its total commissions, commission equivalents, and mark-ups from transactions in securities during that period. The rule also contains an exemption for transactions with established customers, as defined in paragraph (d)(3) of the rule.

Except for the established customer exemption, the Commission is proposing to substitute the exemptions described above with the exemptions under Rule 15g-1.[14] Thus, Rule 15c2-6 would exempt transactions with institutional accredited investors,[15] the issuer of the penny stock, and any director, officer, general partner, or beneficial owner of more than five percent of any class of equity security of the issuer, but would not exempt transactions with other individual accredited investors.[16]

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[6] For a detailed discussion of Rule 3a51-1 and the rationale for the specific exclusions from the definition of penny stock, see Adopting Release.

[7] See also Proposing Release, 56 FR 19176.

[8] *I.e.*, revenues of at least $18 million by the end of the three-year period.

[9] Securities Exchange Act Release No. 30569 (April 10, 1992).

[10] This exclusion is conditioned on the national securities exchange making transaction reports available for at least some securities pursuant to Rule 11Aa3-1 (17 CFR 240.11Aa3-1).

[11] "Reported securities," as defined in 17 CFR 240.11Aa3-1(a)(4), are separately excluded from the definition of penny stock pursuant to paragraph (a) of Rule 3a51-1, and therefore are not required to meet the conditions set forth in paragraph (e) of the rule. *See* Adopting Release.

[12] See House Comm. on Energy and Commerce, Report to accompany the Penny Stock Reform Act of 1990, H.R. Rep. No. 617, 101st Cong. 2d Sess. (July 23, 1990), at 27; and Proposing Release, 56 FR at 19167.

[13] The only difference would be that, in calculating the price of a security for purposes of Rule 15c2-6, broker-dealers would be required to exclude the amount of any commission, commission equivalent, or mark-up charged in both agency and principal transactions.

[14] Moreover, as discussed above, the transactional exemption in Rule 15c2-6 for securities priced at five dollars or more would become a definitional exclusion.

[15] The term "institutional accredited investor" is defined in 17 CFR 230.501(a) (1), (2), (3), (7), and (8).

[16] The term "individual accredited investor" is defined in 17 CFR 230.501(a)(4), (5), and (6).

Continued

Instead, Rule 15c2–6 would provide an exemption for private offerings; that is, the rule would exempt transactions that meet the requirements of Regulation D under the Securities Act, [17] as well as transactions with an issuer not involving any public offering pursuant to Section 4(2) of the Securities Act.[18]

Under the proposed amendments, Rule 15c2–6 would continue to provide an exemption for broker-dealers receiving less than five percent of their total sales-related revenue from transactions in low-priced non-NASDAQ OTC securities. The *de minimis* revenue exemption, however, would be based on transactions in penny stocks, as defined in Rule 3a51–1, rather than transactions in "designated securities," as defined in current Rule 15c2–6(d)(2). As a result, the exemption would be somewhat broader than the current exemption in that it would allow broker-dealers to exclude from their five percent revenue calculation transactions in securities that are priced at five dollars or more.[19] In addition, broker-dealers would have the option of calculating their revenue over a six month period, rather than on a monthly basis.[20]

As the Commission stated in the Adopting Release, in the absence of price and trading information about particular penny stocks and the penny stock market in general, many affluent individual investors have been convinced through abusive sales practices to purchase penny stocks without sufficiently understanding the risks or the nature of their investment. If amended as proposed, Rule 15c2–6 would require broker-dealers to determine that the investor, regardless of his or her affluence, is capable of evaluating the risks of investing in speculative low-priced securities. The rule also would protect these investors from high pressure sales tactics by requiring broker-dealers to obtain the investor's written consent to the transaction.

[17] 17 CFR 230.501 through 230.508.

[18] 15 U.S.C. 77d(2). Assuming that the requirements of either of those provisions have been met, this exemption would apply even if the particular customer involved is not an accredited investor.

[19] Broker-dealers also could exclude transactions based on the average revenues of the issuer. As discussed above, however, broker-dealers would only be able to exclude from their five percent revenue calculation securities that are issued by an issuer with $2 million in net tangible assets if the issuer has been in business for at least three years.

[20] Specifically, amended Rule 15c2–6 would exempt transactions by a broker-dealer whose commissions, commission-equivalents, mark-ups, and mark-downs from transactions in penny stocks during each of the immediately preceding three months and during eleven or more of the preceding twelve months, or during the immediately preceding six months, did not exceed five percent of its total commissions, commission equivalents, mark-ups, and mark-downs from transactions in securities during those months.

Finally, the proposed amendments would not affect Rule 15c2–6's exemption for transactions that are not recommended by a broker-dealer or for transactions in which the purchaser is an established customer of the broker-dealer. Although Rule 15g–1 does not contain an established customer exemption, the Commission is proposing to retain the exemption solely for purposes of Rule 15c2–6. The Commission believes that persons that have previous investment experience in penny stocks or that are familiar with their broker-dealer are less susceptible to high pressure sales tactics and therefore are less in need of the particular protections provided by Rule 15c2–6.

B. Amendments to Schedule 15G

The Commission recently adopted Rule 15g–2 to implement the provisions of section 15(g)(2) of the Exchange Act.[21] The rule makes it unlawful for a broker-dealer to effect a transaction in a penny stock with or for the account of a customer unless the broker-dealer distributes to the customer, prior to effecting a transaction in a penny stock, a document describing the risks of investing in the penny stock market and other relevant information. The risk disclosure document, as set forth in Schedule 15G, contains a brief description of a broker-dealer's obligations under the Penny Stock Rules. To make the document more comprehensive, the Commission is proposing to amend Schedule 15G to include a paragraph describing the duties of a broker-dealer under Rule 15c2–6. Specifically, the following paragraph would be added to the section entitled "Your Rights:"

In addition to the items listed above, your brokerage firm must send to you:

● A Written Statement of Your Financial Situation and Investment Goals. In general, unless you have had an account with your brokerage firm for more than one year, or you have previously bought three different penny stocks from that firm, your brokerage firm must send you a written statement for you to sign that accurately describes your financial situation, your investment experience, and your investment goals, and that contains a statement of why your firm decided that penny stocks are a suitable investment for you. The firm also must get your written consent to buy the penny stock.

III. Conclusion and Request for Comments

The Commission believes that the proposed amendments to Rule 15c2–6 would simplify compliance with the rule and the Penny Stock Rules. The Commission requests comment on whether the amendments as proposed would accomplish this objective. The Commission particularly requests comment on whether the exemption for transactions with established customers should be retained, or whether the definition of "established customer" under the rule should be revised in any respect. The Commission also solicits comment on whether the language proposed to be added to the risk disclosure document clearly communicates the obligations of a broker-dealer under Rule 15c2–6.

[21] *See* Adopting Release.

IV. Effects on Competition and Regulatory Flexibility Act Considerations

Section 23(a) of the Exchange Act [22] requires that the Commission, in adopting rules under the Exchange Act, consider the anticompetitive effects of such rules, if any, and balance any anticompetitive impact against the regulatory benefits gained in terms of furthering the purposes of the Exchange Act. The Commission is preliminarily of the view that the conforming amendments to Rule 15c2–6 would not result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act.

In addition, the Commission has prepared an Initial Regulatory Flexibility Analysis ("IRFA"), pursuant to the requirements of the Regulatory Flexibility Act,[23] regarding the proposed amendments. The IRFA indicates that the proposed amendments would eliminate some of the existing costs imposed on small broker-dealers and small issuers. A copy of the IRFA may be obtained from Belinda Blaine, Attorney, Office of Chief Counsel, Division of Market Regulation, Securities and Exchange Commission, 450 Fifth Street, NW., Mail Stop 5–1, Washington, DC 20549, (202) 504–2418.

List of Subjects in 17 CFR Part 240

Reporting and recordkeeping requirements, Securities.

V. Statutory Basis and Text of Amendments

In accordance with the foregoing, part 240 of chapter II of title 17 of the Code of Federal Regulations is proposed to be amended as follows:

[22] 15 U.S.C. 78w(a)(2).

[23] 5 U.S.C. 603.

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

1. The authority citation for part 240 continues to read as follows:

Authority: 15 U.S.C. 77c, 77d, 77s, 77ttt, 78c, 78d, 78i, 78j, 78l, 78m, 78n, 78o, 78p, 78s, 78w, 78x, 79q, 79t, 80a-29, 80a-37, unless otherwise noted.

2. In § 240.15c2-6, by amending paragraphs (a) introductory text (two places), (a)(2)(ii), and (b)(3)(ii) by removing the words "designated security" and in their place adding the words "penny stock," and by removing the words "designated securities" and in their place adding the words "penny stocks" in paragraphs (a)(2)(i), (b) introductory text, and (b)(2) two places, and by revising paragraphs (c) and (d) to read as follows:

§ 240.15c2-6 Sales practice requirements for certain low-priced securities.

* * * * *

(c) For purposes of this section, the following transactions shall be exempt—

(1) Transactions that are exempt under 17 CFR 240.15g-1.

(2) Transactions in which the purchaser is an established customer of the broker or dealer.

(d) For purposes of this section—

(1) The term "penny stock" shall have the same meaning as in 17 CFR 240.3a51-1.

(2) The term "established customer" shall mean any person for whom the broker or dealer, or a clearing broker on behalf of such broker or dealer, carries an account, and who in such account:

(i) Has effected a securities transaction, or made a deposit of funds or securities, more than one year previously; or

(ii) Has made three purchases of penny stocks that occurred on separate days and involved different issuers.

3. By amending § 240.15g-100 to add to the section entitled "Your Rights," before the paragraph entitled "*Legal remedies*," the following paragraph:

§ 240.15g-100 Schedule 15G—Information to be included in the document distributed pursuant to 17 CFR 240.15g-2.

• A Written Statement of Your Financial Situation and Investment Goals. In general, unless you have had an account with your brokerage firm for more than one year, or you have previously bought three different penny stocks from that firm, your brokerage firm must send you a written statement for you to sign that accurately describes your financial situation, your investment experience, and your investment goals, and that contains a statement of why your firm decided that penny stocks are a suitable investment for you. The firm also must get your written consent to buy the penny stock.

Dated: April 20, 1992.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 92-9604 Filed 4-27-92; 8:45 am]

BILLING CODE 8010-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 30609]

Order Temporarily Exempting Broker-Dealers from Section 15(g)(2) of the Securities Exchange Act of 1934

April 20, 1992.

I

Section 15(g)(2) of the Securities Exchange Act of 1934 (the "Exchange Act") requires a broker-dealer, prior to effecting any transaction in a penny stock, to give the customer a risk disclosure document that contains certain information specified therein. Schedule 15G of Rule 15g–2 specifies the contents and format of the risk disclosure document that broker-dealers are required to distribute. Rule 15g–2 and Schedule 15G become effective on July 15, 1992.

However, pursuant to section 1(c)(3)(B) of the Securities Enforcement Remedies and Penny Stock Reform Act of 1990, section 15(g)(2) became effective prior to the effective date of Rule 15g–2 and Schedule 15G, on April 15, 1992. Section 15(g)(2) therefore has the effect, independent of Rule 15g–2, of requiring broker-dealers to provide a risk disclosure document to customers, without the information and format required in Schedule 15G.

II. Findings

Based on the above, the Commission finds it consistent with the public interest and the protection of investors to exempt retroactively all broker-dealers from the application of section 15(g)(2) of the Exchange Act until the effective date of Rule 15g–2 and Schedule 15G.

III. Order

Accordingly, *It Is Hereby Ordered*, pursuant to section 15(g)(4) of the Exchange Act, that all broker-dealers are exempt from section 15(g)(2) of the Exchange Act until July 15, 1992. This order shall be effective retroactively to the effective date of section 15(g)(2).

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 92–9603 Filed 4–27–92; 8:45 am]

BILLING CODE 8010–01–M

federal register

Tuesday
April 28, 1992

Part IV

National Science Foundation

45 CFR Part 650

Policies and Procedures for Inventions and Patents Resulting From Grants, Cooperative Agreements, and Contracts; Final Rule and Request for Comments

NATIONAL SCIENCE FOUNDATION

45 CFR Part 650

Policies and Procedures For Inventions and Patents Resulting From Grants, Cooperative Agreements, and Contracts

AGENCY: National Science Foundation.

ACTION: Final rule with request for comments.

SUMMARY: This regulation revises the current NSF patent regulation to bring NSF patent policies and procedures into compliance with the amended chapter 18 of title 35 of the United States Code and the guidance published by the Department of Commerce as part 401 of title 37 of the Code of Federal Regulations. The policies and procedures set forth apply to all contracts, grants, and cooperative agreements awarded by the Foundation.

DATES: This revision is effective April 28, 1992. Comments, however, are welcome and will be considered in making future revisions.

ADDRESSES: All comments should be addressed to: NSP Patent Assistant, Office of the General Counsel, room 501, National Science Foundation, Washington, DC 20550.

FOR FURTHER INFORMATION CONTACT: April C. Bennett, NSF Patent Assistant, at (202) 357–9435 (voice) or (202) 357–7521 (facsimile)—those are not toll-free numbers—or by electronic mail as patents@nsf through BITNET or patents@nsf.gov through INTERNET.

SUPPLEMENTARY INFORMATION: This amendment revises the current NSF patent regulation published as part 650 of title 45 of the Code of Federal Regulations to bring it into compliance with the amended chapter 18 of title 35 of the United States Code (commonly called the "Bayh-Dole Act") and the guidance published by the Department of Commerce as part 401 of title 37 of the Code of Federal Regulations. Because it merely implements the amended statute and Government-wide guidance that was subject to public comment, public comments were not obtained before making this regulation effective.

Throughout the regulation, references to OMB Circular A–124 have been replaced by ones to the Department of Commerce guidance published as part 401 of title 37 of the Code of Federal Regulations. The titles of "Intellectual Property Attorney" and "NSF Patent Paralegal" has been deleted and the duties formerly assigned those positions given to an "NSF Patent Assistant" because experience since enactment of the Bayh-Dole Act has shown that processing of invention disclosures and waiver requests does not require legal or paralegal training. Requirements for obtaining the concurrence of the NSF Program Officer, NSF Grants or Contracts Officer, or both before transferring patent rights or administrative responsibility for an invention to another agency (§§ 650.9 & 650.10) were eliminated as unnecessary. Similar requirements for waiving deadlines and restrictions imposed by the standard Patent Rights clause [§ 650.12(a)–(c)] also have been eliminated to streamline approval of such requests, as urged in the DOC guidance.

In paragraph (a) of § 650.2, NSF Patent Policy, the reference to the "Office of Management and Budget" has been changed to the "Department of Commerce". The statement that the standard clause will be used in contracts for operation of Government-owned facilities has been deleted both because the 1984 amendments to the Bayh-Dole Act and DOC's implementing guidance make that the norm and because the Foundation no longer has such contracts. A statement that the standard clause normally will be used in awards to foreign entities was added because the amended statute and DOC regulation would allow such entities to be treated differently.

The former paragraph (c) of § 650.2 has been deleted since the policy of claiming no rights to inventions in fellowships and traineeships is now mandated by section 212 of the Bayh-Dole Act. The two following paragraphs were redesignated.

What is now paragraph (c) of § 650.2 has been revised to give the employer of an inventor, even if not an NSF awardee, an opportunity to object to the Foundation's allowing the inventor to retain rights to an invention unwanted by the awardee. This addresses the situation where the subject invention is made jointly by an NSF-assisted university researcher and a person funded by non-NSF sources and is intended to give the Foundation some flexibility when there is an employer-employee dispute without calling into question an employee-inventor's ability to retain principal patent rights under other circumstances.

The former paragraph (f) of § 650.2 has been deleted because the Bayh-Dole Act no longer restricts exclusive licensing by nonprofit organizations and requests for approval of assignments are rare.

The former paragraph (g) of § 650.2 was deleted because section 210(c) of the Bayh-Dole Act now requires NSF to obtain the rights secured by the standard clause to all subject inventions.

The former paragraph (h) of § 650.2, which stated that the NSF Patent Policy applied to funding agreements pre-dating the Bayh-Dole Act was deleted as unnecessary.

The standard patent rights clause published in § 650.4 was modified to conform to that prescribed at § 401.14 of title 37 of the Code of Federal Regulations.

Responsibility for negotiating special patent provisions, including rights to inventions owned by a potential awardee, is given to the Grants or Contracts Officer, who would negotiate other award terms (§§ 650.5 and 650.16). In the decade since the Bayh-Dole Act became effective, the Foundation has never found it necessary to negotiate a special Patent Rights clause. Legal advice will be available from the Office of the General Counsel if needed.

Paragraph (a)(2) of § 650.5, which stated criteria on which special provisions might be negotiated for awards not covered by the Bayh-Dole Act, has been eliminated because, as noted above, section 210(c) of that Act now requires that the minimal Government rights be obtained to all subject inventions.

Former § 650.8, Requests for greater rights, has been eliminated because disclosures are no longer being received for inventions made under pre-Bayh-Dole awards containing deferred-determination clauses. Should a deferred-determination clause be used in a special patent provision, inventions subject to it will be processed under the general waiver procedures, § 650.12(d).

As in the Patent Policy statement, the conditions under which the Foundation will not automatically allow an inventor to retain principal patent rights have been expanded to include situations where the employer of the inventor shows that it would be harmed (§ 650.8). Since most inventors will be employees of awardees, this change will have little effect.

Section 650.12 gives responsibility for approving exceptions to or waiving administrative requirements to the Patent Assistant alone, rather than to the Intellectual Property Attorney with a requirement for consultation with the Program Officer and Grants or Contracts Officer. Consistent with the responsibility for negotiating special patent provisions, the Grants or Contracts Officer is authorized to waive such provisions. Procedures for asking for approval or waiver have been rewritten to allow for electronic

submission and to reduce the paperwork required to request and approve deadline waiver requests.

Both § 650.13, Exercise of march-in rights, and § 650.14, Request for conveyance of title to NSF, have been revised to conform to the DOC guidance.

Section 650.15 now provides that all appeals, other than those of the General Counsel's decisions to march in upon or request conveyance of an invention, will be handled by the Director of the Division of Grants and Contracts.

The Foundation has determined that this regulation is not a major rule as defined in Executive Order 12291 of February 17, 1981 (3 CFR, 1981 Comp., p. 127).

List of Subjects in 45 CFR Part 650

Government procurement; Grant programs—science and technology; Inventions and patents; Nonprofit organizations; Small businesses.

Walter E. Massey,

Director.

Accordingly, title 45 of the Code of Federal Regulations is amended by revising part 650 to read as follows:

PART 650—PATENTS

Sec.
650.1 Scope of part.
650.2 National Science Foundation patent policy.
650.3 Source of authority.
650.4 Standard patent rights clause.
650.5 Special patent provisions.
650.6 Awards not primarily for research.
650.7 Awards affected by international agreements.
650.8 Retention of rights by inventor.
650.9 Unwanted inventions.
650.10 Inventions also supported by another Federal agency.
650.11 Utilization reports.
650.12 Waivers and Approvals.
650.13 Exercise of march-in rights.
650.14 Request for conveyance of title to NSF.
650.15 Appeals.
650.16 Background rights.
650.17 Subcontracts.
650.18 Delegation of authority.
Appendix A to part 650—Optional format for confirmatory license.

Authority: 35 U.S.C. 200–212, 42 U.S.C. 1870(e) and 1871; and the Presidential Memorandum entitled "Government Patent Policy", issued February 18, 1983.

§ 650.1 Scope of part.

This part contains the policies, procedures, and clauses that govern allocation of rights to inventions made in performance of NSF-assisted research. It applies to all current and future funding agreements entered into by the Foundation that relate to performance of scientific or engineering research. As stated in the NSF Acquisition Regulation (chapter 25 of title 48 of the Code of Federal Regulations), this part applies to contracts as well as to grants and cooperative agreements.

§ 650.2 National Science Foundation patent policy.

As authorized by the National Science Board at its 230th meeting, October 15–16, 1981, the Director of the National Science Foundation has adopted the following statement of NSF patent policy.

(a) In accordance with the Bayh-Dole Act and the Presidential Memorandum entitled "Government Patent Policy" issued February 18, 1983, the Foundation will use the Patent Rights clause prescribed by the Department of Commerce in all its funding agreements for the performance of experimental, developmental, or research work, including awards made to foreign entities, unless the Foundation determines that some other provision would better serve the purposes of that Act or the interests of the United States and the general public.

(b) In funding agreements covered by a treaty or agreement that provides that an international organization or foreign government, research institute, or inventor will own or share patent rights, the Foundation will acquire such patent rights as are necessary to comply with the applicable treaty or agreement.

(c) If an awardee elects not to retain rights to an invention, the Foundation will allow the inventor to retain the principal patent rights unless the awardee, or the inventor's employer if other than the awardee, shows that it would be harmed by that action.

(d) The Foundation will normally allow any patent rights not wanted by the awardee or inventor to be dedicated to the public through publication in scientific journals or as a statutory invention registration. However, if another Federal agency is known to be interested in the relevant technology, the Foundation may give it an opportunity to review and patent the invention so long as that does not inhibit the dissemination of the research results to the scientific community.

§ 650.3 Source of authority.

(a) 35 U.S.C. 200–212, commonly called the Bayh-Dole Act, as amended by title V of Public Law 98–620 (98 stat. 3335, 3364). That law controls the allocation of rights to inventions made by employees of small business firms and domestic nonprofit organizations, including universities, during federally-supported experimentation, research, or development. Government-wide implementing regulations are contained in part 401 of title 37 of the Code of Federal Regulations.

(b) Section 11(e) of the National Science Foundation Act of 1950, as amended, (42 U.S.C. 1870(e)) provides that the Foundation shall have the authority to do all things necessary to carry out the provisions of this Act, including, but without being limited thereto, the authority—to acquire by purchase, lease, loan, gift, or condemnation, and to hold and dispose of by grant, sale, lease, or loan, real and personal property of all kinds necessary for, or resulting from, the exercise of authority granted by this Act.

(c) Section 12 of the NSF Act (42 U.S.C. 1871) provides that each contract or other arrangement executed pursuant to this Act which relates to scientific research shall contain provisions governing the disposition of inventions produced thereunder in a manner calculated to protect the public interest and the equities of the individual or organization with which the contract or other arrangement is executed.

(d) The Presidential Memorandum entitled "Government Patent Policy issued February 18, 1983, directs Federal agencies, to the extent permitted by law, to apply to all research performers the policies of the Bayh-Dole Act. Under the provisions of the National Science Foundation Act quoted above, the Foundation is permitted to apply the Bayh-Dole policies without restriction.

§ 650.4 Standard patent rights clause.

(a) The following Patent Rights clause will be used in every funding agreement awarded by the Foundation that relates to scientific or engineering research unless a special patent clause has been negotiated (see § 650.5).

Patent Rights (April, 1992)

(a) *Definitions.*—(1) *Invention* means any invention or discovery which is or may be patentable or otherwise protectable under title 35 of the United States Code, to any novel variety of plant which is or may be protected under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).

(2) *Subject invention* means any invention of the grantee conceived or first actually reduced to practice in the performance of work under this grant, provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act (7 U.S.C. 2401(d)) must also occur during the period of grant performance.

(3) *Practical application* means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its

benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.

(4) *Made* when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(5) *Small business firm* means a domestic small business concern as defined at section 2 of Public Law 85–536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this Patents Rights clause, the size standard for small business concerns involved in Government procurement and subcontracting at 13 CFR 121.3–8 and 13 CFR 121.3–12, respectively, will be used.

(6) *Nonprofit organization* means a domestic university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any domestic nonprofit scientific or educational organization qualified under a State nonprofit organization statute.

(b) *Allocation of Principal Rights.* The grantee may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions of this Patents Rights clause and 35 U.S.C. 203. With respect to any subject invention in which the grantee retains title, the Federal Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world. If the award indicates it is subject to an identified international agreement or treaty, the National Science Foundation (NSF) also has the right to direct the grantee to convey to any foreign participant such patent rights to subject inventions as are required to comply with that agreement or treaty.

(c) *Invention Disclosure, Election of Title and Filing of Patent Applications by Grantee.* (1) The grantee will disclose each subject invention to NSF within two months after the inventor discloses it in writing to grantee personnel responsible for the administration of patent matters. The disclosure to NSF shall be in the form of a written report and shall identify the grant under which the invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding of the nature, purpose, operation, and, to the extent known, the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. In addition, after disclosure to NSF, the grantee will promptly notify NSF of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the grantee.

(2) The grantee will elect in writing whether or not to retain title to any such invention by notifying NSF within two years of disclosure to NSF. However, in any case where publication, on sale, or public use has initiated the one year statutory period wherein valid patent protection can still be obtained in the United States, the period for election of title may be shortened by NSF to a date that is no more than 60 days prior to the end of the statutory period.

(3) The grantee will file its initial patent application on an invention to which it elects to retain title within one year after election of title or, if earlier, prior to the end of any statutory period wherein valid patent protection can be obtained in the United States after a publication, on sale, or public use. The grantee will file patent applications in additional countries or international patent offices within either ten months of the corresponding initial patent application, or six months from the date when permission is granted by the Commissioner of Patents and Trademarks to file foreign patent applications when such filing has been prohibited by a Secrecy Order.

(4) Requests for extension of the time for disclosure to NSF, election, and filing under subparagraphs (c) (1), (2), and (3) of this clause may, at the discretion of NSF, be granted.

(d) *Conditions When the Government May Obtain Title.* The grantee will convey to NSF, upon written request, title to any subject invention:

(1) If the grantee fails to disclose or elect the subject invention within the times specified in paragraph (c) above, or elects not to retain title; provided that NSF may only request title within 60 days after learning of the failure of the grantee to disclose or elect within the specified times.

(2) In those countries in which the grantee fails to file patent applications within the times specified in paragraph (c) above; provided, however, that if the grantee has filed a patent application in a country after the times specified in paragraph (c) above, but prior to its receipt of the written request of NSF, the grantee shall continue to retain title in that country.

(3) In any country in which the grantee decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in a reexamination or opposition proceeding on, a patent on a subject invention.

(e) *Minimum Rights to Grantee.* (1) The grantee will retain a nonexclusive royalty-free license throughout the world in each subject invention to which the Government obtains title, except if the grantee fails to disclose the subject invention within the times specified in paragraph (c) above. The grantee's license extends to its domestic subsidiaries and affiliates, if any, within the corporate structure of which the grantee is a party and includes the right to grant sublicenses of the same scope to the extent the grantee was legally obligated to do so at the time the grant was awarded. The license is transferable only with the approval of NSF except when transferred to the successor of that part of the grantee's business to which the invention pertains.

(2) The grantee's domestic license may be revoked or modified by NSF to the extent necessary to achieve expeditious practical application of the subject invention pursuant to an application for an exclusive license submitted in accordance with applicable provisions at 37 CFR part 404. This license will not be revoked in that field of use or the geographical areas in which the grantee has achieved practical application and continues to make the benefits of the invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of NSF to the extent the grantee, its licensees, or its domestic subsidiaries or affiliates have failed to achieve practical application in that foreign country.

(3) Before revocation or modification of the license, NSF will furnish the grantee a written notice of its intention to revoke or modify the license, and the grantee will be allowed thirty days (or such other time as may be authorized by NSF for good cause shown by the grantee) after the notice to show cause why the license should not be revoked or modified. The grantee has the right to appeal, in accordance with applicable regulations in 37 CFR part 404 concerning the licensing of Government-owned inventions, any decision concerning the revocation or modification of its license.

(f) *Grantee Action to Protect Government's Interest.* (1) The grantee agrees to execute or to have executed and promptly deliver to NSF all instruments necessary to:

(i) Establish or confirm the rights the Government has throughout the world in those subject inventions for which the grantee retains title, and

(ii) Convey title to NSF when requested under paragraph (d) above, and to enable the Government to obtain patent protection throughout the world in that subject invention.

(2) The grantee agrees to require, by written agreement, its employees, other than clerical and non-technical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the grantee each subject invention made under this grant in order that the grantee can comply with the disclosure provisions of paragraph (c) above, and to execute all papers necessary to file patent applications on subject inventions and to establish the Government's rights in the subject inventions. The disclosure format should require, as a minimum, the information requested by paragraph (c)(1) above. The grantee shall instruct such employees through the employee agreements or other suitable educational programs on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The grantee will notify NSF of any decision not to continue prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than thirty days before the expiration of the response period required by the relevant patent office.

(4) The grantee agrees to include, within the specification of any United States patent

application and any patent issuing thereon covering a subject invention, the following statement: "This invention was made with Government support under (identify the grant) awarded by the National Science Foundation. The Government has certain rights in this invention."

(5) The grantee or its representative will complete, execute, and forward to NSF a confirmation of a License to the United States Government within two months of filing any domestic or foreign patent application.

(6) The grantee or its representative will forward to NSF a copy of any United States patent covering a subject invention within two months after it is issued.

(g) *Subcontracts.* (1) The grantee will include this Patents Rights clause, suitably modified to identify the parties, in all subcontracts, regardless of tier, for experimental, developmental, or research work. The subcontractor will retain all rights provided for the grantee in this Patents Rights clause, and the grantee will not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions.

(2) In the case of subcontracts, at any tier, when the prime award by the Foundation was a contract (but not a grant or cooperative agreement), NSF, subcontractor, and contractor agree that the mutual obligations of the parties created by this Patents Rights clause constitute a contract between the subcontractor and the Foundation with respect to those matters covered by this Patents Rights clause.

(h) *Reporting on Utilization of Subject Inventions.* The grantee agrees to submit on request periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by the grantee or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the grantee, and such other data and information as NSF may reasonably specify. The grantee also agrees to provide additional reports in connection with any march-in proceeding undertaken by NSF in accordance with paragraph (j) of this Patents Rights clause. As required by 35 U.S.C. 202(c)(5), NSF agrees it will not disclose such information to persons outside the Government without the permission of the grantee.

(i) *Preference for United States Industry.* Notwithstanding any other provision of this Patents Rights clause, the grantee agrees that neither it nor any assignee will grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by NSF upon a showing by the grantee or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

(j) *March-in Rights.* The grantee agrees that with respect to any subject invention in which it has acquired title, NSF has the right in accordance with procedures at 37 CFR 401.6 and NSF regulations at 45 CFR 650.13 to require the grantee, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the grantee, assignee, or exclusive licensee refuses such a request, NSF has the right to grant such a license itself if NSF determines that:

(1) Such action is necessary because the grantee or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

(2) Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the grantee, assignee, or their licensees;

(3) Such action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the grantee, assignee, or licensee; or

(4) Such action is necessary because the agreement required by paragraph (i) of this Patents Rights clause has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of such agreement.

(k) *Special Provisions for Grants with Nonprofit Organizations.* If the grantee is a nonprofit organization, it agrees that:

(1) Rights to a subject invention in the United States may not be assigned without the approval of NSF, except where such assignment is made to an organization which has as one of its primary functions the management of inventions, provided that such assignee will be subject to the same provisions as the grantee;

(2) The grantee will share royalties collected on a subject invention with the inventor, including Federal employee co-inventors (when NSF deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) The balance of any royalties or income earned by the grantee with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, will be utilized for the support of scientific research or education; and

(4) It will make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business firms and that it will give preference to a small business firm if the grantee determines that the small business firm has a plan or proposal for marketing the invention which, if executed, is equally likely to bring the invention to practical application as any plans or proposals from applicants that are not small business firms; provided that the grantee is also satisfied that the small business firm has the capability and resources to carry out it plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the grantee. However, the grantee agrees that the Secretary of Commerce may review the grantee's licensing program and decisions regarding small business applicants, and the grantee will negotiate changes to its licensing policies, procedures, or practices with the Secretary when the Secretary's review discloses that the grantee could take reasonable steps to implement more effectively the requirements of this paragraph (k)(4).

(l) *Communications.* All communications required by this Patents Rights clause should be sent to: Patent Assistant, Office of the General Counsel, National Science Foundation, Washington, DC 20550.

(b) When the above Patent Rights clause is used in a funding agreement other than a grant, "grant" and "grantee" may be replaced by "contract" and "contractor" or other appropriate terms.

(Approved by the Office of Management and Budget under control number 3145–0084)

§ 650.5 Special patent provisions.

At the request of the prospective awardee or on recommendation from NSF staff, a Grants or Contracts Officer, with the concurrence of the cognizant Program Manager, may negotiate special patent provisions when he or she determines that exceptional circumstances require restriction or elimination of the right of a prospective awardee to retain title to any subject invention in order to better promote the policy and objectives of chapter 18 of title 35 of the United States Code or the National Science Foundation Act. The Grants or Contracts Officer will prepare the written determination required by § 401.3(e) of title 37 of the Code of Federal Regulations and assure that appropriate reports are made to the Secretary of Commerce and Chief Counsel for Advocacy of the Small Business Administration as required in § 401.3(f). Unless doing so would be inconsistent with an obligation imposed on the Foundation by statute, international agreement, or pact with other participants in or supporters of the research, every special patent provision will allow the awardee, after an invention has been made, to request that it be allowed to retain principal rights to that invention under § 650.12(e) of this regulation.

§ 650.6 Awards not primarily for research.

(a) Awards not primarily intended to support scientific or engineering research need contain no patent provision. Examples of such awards are travel and conference grants.

(b) NSF fellowships and traineeships are primarily intended to support education or training, not particular research. Therefore, in accordance with section 212 of title 35 of the United States Code, the Foundation claims no rights to inventions made by fellows or trainees. The following provision will be included in each fellowship or traineeship program announcement and made part of the award:

Intellectual Property Rights

The National Science Foundation claims no rights to any inventions or writings that might result from its fellowship or traineeship awards. However, fellows and trainees should be aware that the NSF, another Federal agency, or some private party may acquire such rights through other support for particular research. Also, fellows and trainees should note their obligation to include an Acknowledgment and Disclaimer in any publication.

§ 650.7 Awards affected by international agreements.

(a) Some NSF awards are made as part of international cooperative research programs. The agreements or treaties underlying many of these programs require an allocation of patent rights different from that provided by the Patent Rights clause in § 650.4(a). Therefore, as permitted by § 401.5(d) of the implementing regulations for the Bayh-Dole Act (37 CFR 401.5(d)), paragraph (b) of the standard Patent Rights clause in § 650.4(a) has been modified to provide that the Foundation may require the grantee to transfer to a foreign government or research performer such rights in any subject invention as are contemplated in the international agreement. The award instrument will identify the applicable agreement or treaty.

(b) After an invention is disclosed to the Patent Assistant, the recipient of an award subject to an international agreement will be informed as to what rights, if any, it must transfer to foreign participants. Recipients may also ask the Program Manager to provide them with copies of the identified international agreements before or after accepting an award.

§ 650.8 Retention of rights by inventor.

If an awardee elects not to retain rights to an invention, the inventor may request the NSF Patent Assistant for permission to retain principal patent rights. Such requests should be made as soon as possible after the awardee notifies the Patent Assistant that it does not want to patent the invention. Such requests will normally be granted unless either the awardee or the employer of the inventor shows that it would be harmed by that action. As required by § 401.9 of the implementing regulations for the Bayh-Dole Act (37 CFR 401.9), the inventor will be subject to the same conditions that the awardee would have been, except that the special restrictions imposed on nonprofit organizations will not apply to the inventor.

§ 650.9 Unwanted inventions.

(a) The Foundation will normally allow any patent rights not wanted by the awardee or inventor to be dedicated to the public through publication in scientific and engineering journals or as a statutory invention registration under section 157 of title 35 of the United States Code. Except as provided in paragraph (b) of this section, the NSF Patent Assistant will acknowledge a negative election by encouraging the awardee and inventor to promptly make all research results available to the scientific and engineering community.

(b) If the NSF Patent Assistant believes that another Federal agency is interested in the relevant technology, he or she may, after receiving the awardee's election not to patent and ascertaining that the inventor also does not want to patent, send a copy of the invention disclosure to that agency to give it an opportunity to review and patent the invention. Unless the agency expresses an interest in the invention within thirty days, the Patent Assistant will acknowledge the awardee's negative election by encouraging prompt publication of all research results. If the agency does express an interest in patenting the invention, the Patent Assistant will transfer to it all rights to the invention.

§ 650.10 Inventions also supported by another Federal Agency.

Section 401.13(a) of the implementing regulation for the Bayh-Dole Act (37 CFR 401.13(a)) provides that in the event that an invention is made under funding agreements of more than one federal agency, the agencies involved will, at the request of the grantee or contractor or on their own initiative, designate one agency to be responsible for the administration of the invention. Whenever the NSF Patent Assistant finds that another agency also supported an NSF subject invention, he or she will consult with the grantee or contractor and appropriate personnel in the other agency to determine if a single agency should be designated to administer the Government's rights in the invention. The Patent Assistant may transfer to, or accept from, any other Federal agency, responsibility for administering a jointly-supported invention.

§ 650.11 Utilization reports.

Paragraph (h) of the standard Patent Rights clause set forth in § 650.4 obliges grantees "to submit on request periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining such utilization". At this time, the Foundation does not plan to request such reports except in connection with march-in investigations conducted under § 650.14. This section will be amended to describe periodic reporting requirements if such are ever established.

§ 650.12 Waivers and approvals.

(a) Requests for extension of time to disclose to the NSF Patent Assistant, make an election to retain title to, or file a patent on a subject invention will be granted by the NSF Patent Assistant unless he or she determines that such an extension would either imperil the securing of valid patent protection or unacceptably restrict the publication of the results of the NSF-supported research.

(b) Approval of assignments by nonprofit organizations (required by subparagraph (k)(1) of the Patent Rights clause in § 650.4(a)) will be given by the Patent Assistant unless he or she determines that the interests of the United States Government will be adversely affected by such assignment.

(c) Approval of long-term exclusive licensing of NSF-assisted inventions by nonprofit organizations (restricted by earlier versions of the NSF Patents Rights clause and by pre-Bayh-Dole Institutional Patent Agreements and waiver conditions) will be given by the Patent Assistant unless he or she determines that the interests of the United States Government will be adversely affected by such waiver.

(d) The preference for United States industry imposed by paragraph (i) of the Patent Rights clause in § 650.4(a) may be waived by the NSF Patent Assistant as provided in that paragraph.

(e) Special restrictions on or limitation of the right of an awardee to retain title to subject inventions imposed under § 650.5 of this regulation may be waived by the Grants or Contracting Officer whenever he or she determines, after consultation with the cognizant Program Manager, that the reasons for imposing the restrictions or limitations do not require their application to a particular invention.

(f) Requests for approvals and waiver under this section should be addressed to the NSF Patent Assistant as provided in paragraph (1) of the Patent Rights clause in § 650.4(a). Requests under paragraph (a) of this section for extensions of time to disclose, elect, or file may be made by telephone or electronic mail as well as in writing. A written request for extension of time to disclose, elect, or file can be assumed to have been approved unless the Patent Assistant replies negatively within ten business days of the date such request was mailed, telecopied, or otherwise dispatched. Requests for approvals or waivers under paragraphs (b), (c), (d), and (e) of this section must be in writing and should explain why an approval or waiver is justified under the stated criteria. The requester will be given a written explanation of the reasons for denial of a request covered by this section.

§ 650.13 Exercise of march-in rights.

(a) The procedures established by this section supplement those prescribed by § 401.6 of the implementing regulation for the Bayh-Dole Act (37 CFR § 401.6) and apply to all march-in rights held by NSF including those resulting from funding agreements not covered by the Bayh-Dole Act.

(b) Petitions requesting that the NSF exercise a march-in right should be addressed to the NSF Patent Assistant. Such petitions should:

(1) Identify the patent or patent application involved and the relevant fields of use of the invention;

(2) State the grounds for the proposed march-in;

(3) Supply evidence that one or more of the four conditions creating a march-in right (lack of practical application, unsatisfied health or safety needs, unmet requirements for public use, or failure to prefer United States industry) is present; and

(4) Explain what action by the Foundation is necessary to correct that condition.

(c) If evidence received from a petitioner or from the Foundation's administration of the Patent Rights clause indicates that one or more of the four conditions creating a march-in right might exist, the NSF Patent Assistant will informally review the matter as provided in § 401.6(b) of the implementing regulation. If that informal review indicates that one or more of the four conditions creating a march-in right probably exists, the Patent Assistant will initiate a formal march-in proceeding by issuing a written notice to the patent holder. That notice will provide all the information required by § 401.6(c) of the implementing regulation. The patent holder may submit information and argument in opposition to the proposed march-in in person, in writing, or through a representative.

(d) If the NSF Patent Assistant determines that a genuine dispute over material facts exists, he or she will identify the disputed facts and notify the NSF General Counsel. The General Counsel will create a cross-directorate fact-finding panel, which will establish its own fact-finding procedures within the requirements of § 401.6(e) of the implementing regulation based on the dimensions of the particular dispute. The Patent Assistant will serve as secretary to the panel, but will not take part in its deliberations. Written findings of facts will be submitted to the General Counsel, sent by certified mail to the patent holder, and made available to all other interested parties.

(e) The NSF General Counsel will determine whether and how the Foundation should exercise a march-in right as provided in § 401.6(g) of the implementing regulation.

§ 650.14 Request for conveyance of title to NSF.

(a) The procedures established by this section apply to the exercise of the Foundation's right under paragraph (d) of the Patent Rights clause in § 650.4(a) to request conveyance of title to a subject invention if certain conditions exist.

(b) The NSF Patent Assistant may request the recipient of an NSF award to convey to the Foundation or a designee title in one or more countries to any invention to which the awardee has elected not to retain title. The NSF Patent Assistant may request immediate conveyance of title to a subject invention if the awardee fails (1) to submit a timely invention disclosure, (2) to make a timely election to retain patent rights, or (3) to file a timely patent application; but only if he or she determines that such action is required to preserve patent rights.

(c) The NSF Patent Assistant will informally review any apparent failure by an awardee to comply with the requirements of paragraph (c) of the Patent Rights clause in § 650.4(a). The interested institution, the inventor, the patent holder, and any other interested party will be given an opportunity to explain why a particular invention was not disclosed, why an election was not made, or why a patent application was not filed. If the Patent Assistant determines that a genuine dispute over material facts exists, a cross-directorate fact-finding panel will be appointed by the General Counsel. The panel will establish its own fact-finding procedures based on the dimensions of the particular dispute. Written findings of facts will be submitted to the General Counsel, sent by certified mail to the patent holder, and made available to all other interested parties.

(d) The NSF General Counsel will determine whether the Foundation should request conveyance of title or if it should retain title obtained under § 650.14(b).

§ 650.15 Appeals.

(a) All actions by the NSF Patent Assistant under § 650.8 denying an inventor's request to retain rights to a subject invention, under § 650.12 denying a request for waiver, or under § 650.14(d) denying the existence of a material dispute may be appealed to the Director of the NSF Division of Grants and Contracts by an affected party within thirty days. A request under § 650.14(b) to immediately convey title to the Foundation may be appealed to the DGC Director by the title holder within five days.

(b) All actions by a Grants of Contracts Officer refusing to eliminate restrictions on or limitation of the right of an awardee to retain title to subject inventions imposed under § 650.5 of this regulation may be appealed to the Director of the NSF Division of Grants and Contracts by an affected party within thirty days.

(c) A decision by the General Counsel to exercise a march-in right or to request conveyance of title may be appealed by the patent holder or any affected licensee to the NSF Deputy Director within thirty days. When a march-in was initiated in response to a petition, the General Counsel's decision not to exercise a march-in right or to exercise it in a manner different from that requested in the petition may be appealed by the petitioner to the NSF Deputy Director within thirty days.

(d) In reviewing the actions of the NSF Patent Assistant, a Grants of Contracts Officer, or the General Counsel, the DGC Director or NSF Deputy Director will consider both the factual and legal basis for the action or determination and its consistency with the policies and objectives of the Foundation and, if applicable, the Bayh-Dole Act (35 U.S.C. 200–212) and implementing regulations at part 401 of title 37 of the Code of Federal Regulations.

§ 650.16 Background rights.

The Foundation will acquire rights to a research performer's pre-existing technology only in exceptional

circumstances where, due to the nature of the research being supported, the Foundation requires greater control over resulting inventions. The NSF Grants or Contracts Officer, with concurrence of the cognizant Program Manager, will negotiate a background rights provision. If the affected awardee is a small business firm or nonprofit organization, the provision will conform to the requirements of the Bayh-Dole Act (35 U.S.C. 202(f)) as implemented by 37 CFR 401.12).

§ 650.17 Subcontracts.

As provided in paragraph (g) of the Patent Rights clause in § 650.4(a), awardees should normally use that clause in all subcontracts. At the request of the awardee or subcontractor or on recommendation from NSF staff, the cognizant Grants or Contracts Officer may direct the awardee to insert into subcontracts relating to scientific research a special patent provision negotiated under § 650.5.

§ 650.18 Delegation of Authority.

The General Counsel is responsible for implementing this regulation and is authorized to make any exceptions to or extensions of the NSF Patent Policy as may be required by particular circumstances. The General Counsel will designate the NSF Patent Assistant and that individual is authorized to carry out the functions assigned by this regulation.

Appendix A to Part 650—Optional Format for Confirmatory License

The following format may be used for the confirmatory license to the Government required by subparagraph (f)(5) of the Patent Rights clause in § 650.4(a). Any equivalent instrument may also be used.

License to the United States Government

This instrument confirms to the United States Government, as represented by the National Science Foundation, an irrevocable, nonexclusive, nontransferable, royalty-free license to practice or have practiced on its behalf throughout the world the following subject invention:

(invention title)

(inventor[s] name[s])

(patent application number and filing date)

(country, if other than United States)

(NSF Disclosure No.).

This subject invention was made with NSF support through:

(grant or contract number)

(grantee or contractor).

Principal rights to this subject invention have been left with the licensor.

Signed: _____

Name: _____

Title: _____

Date: _____

Accepted on behalf of the Government:

_____

NSF Patent Assistant

Date: _____

[FR Doc. 92-9640 Filed 4-27-92; 8:45 am]

BILLING CODE 7555-01-M

federal register

Tuesday
April 28, 1992

Part V

Department of the Interior

Bureau of Indian Affairs

Fiscal Year 1992–1994 Plan for Services to Indian Children With Disabilities and Their Families; Notice of Public Hearings

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Fiscal Year 1992–1994 Plan for Services to Indian Children With Disabilities and Their Families

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of public hearings.

SUMMARY: Notice is hereby given that the Office of Indian Education Programs (OIEP), Branch of Exceptional Education, has completed the required application "State Plan" for funds under Part B of the Individuals with Disabilities Education Act, Public Law 101–476. The application describes activities that will provide education and related services for Indian Children with Disabilities (ages 5–21) served by elementary and secondary schools funded by the Bureau of Indian Affairs, Department of the Interior.

The application is available to all interested parties and members of the general public. Each BIA Area/Agency Education will have copies of the application available for inspection. In addition, copies may be obtained from the Branch of Exceptional Education by calling (202) 208–6675.

Public hearings will be held at some school locations. Persons interested in making public comment should contact the local BIA Area/Agency Education Offices listed below for more information. Individuals who make public comment are encouraged to submit a written statement summarizing their comments to the proctor at the actual hearing.

DATES: Written comments must be received at the address listed below no later than May 10, 1992:

ADDRESSES: Office of Indian Education Programs, Branch of Exceptional Education, Attn: Marie J. Emery, MS 3530 MIB Code 523, 1849 C Street, NW., Washington, DC 20240–4000.

FOR FURTHER INFORMATION CONTACT: Goodwin K. Cobb, III at the above address or call (202) 208–6675, FAX (202) 208–5993. Office of Indian Education Programs, Branch of Exceptional Education, MS 3530 MIB Code 523, 1849 C Street NW., Washington, DC 20240–4000.

Dated: April 17, 1992.

William D. Bettenberg,

Acting Assistant Secretary—Indian Affairs.

[FR Doc. 92–9712 Filed 4–27–92; 8:45 am]

BILLING CODE 4310–02–M

federal register

Tuesday
April 28, 1992

Part VI

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 807

Medical Devices; Substantial Equivalence; 510(k) Summaries and Statements; Class III Summaries; Confidentiality of Information; Interim Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 807

[Docket No. 91N-0388]

Medical Devices; Substantial Equivalence; 510(k) Summaries and 510(k) Statements; Class III Summaries; Confidentiality of Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing an interim rule to implement provisions of the Safe Medical Devices Act of 1990 (SMDA) which require persons who submit a premarket notification to provide to FDA, as part of the submission, an adequate summary of any information respecting safety and effectiveness or a statement that such information will be made available upon request by any person. The interim rule prescribes the content and format of these submissions. The interim rule also implements the requirement that 510(k) submitters, claiming substantial equivalence to a class III preamendments device for which FDA has not yet called for premarket approval, submit a class III summary and certify that they have conducted a search of safety and effectiveness data. In addition, the interim rule amends the medical device regulations governing the confidentiality of certain premarket notification submissions and their summaries to conform to the SMDA. FDA is also requiring that persons who submit a premarket notification (510(k)) certify that the data and information are truthful and accurate and that no material fact has been omitted.

DATES: Written comments by June 29, 1992. This interim rule will become effective May 28, 1992.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ-404), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301-427-1190.

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Authority and Legislative History

On May 28, 1976, Congress enacted the Medical Device Amendments of 1976 (Pub. L. 94-295) (the amendments), which amended the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*) to expand FDA's authority to regulate the introduction of medical devices into interstate commerce and thereby ensure their safety and effectiveness. Section 510(k) of the act (21 U.S.C. 360(k)) authorizes FDA to issue regulations to require persons who propose to begin commercial distribution of a device intended for human use into interstate commerce to report to FDA the class in which the device is classified under section 513 of the act (21 U.S.C. 360c) or, if such person determines that the device is not classified under such section, a statement of that determination and the basis for the determination that the device is or is not so classified. This premarket notification must be furnished to FDA at least 90 days before introduction of the device into commercial distribution. On August 23, 1977, FDA issued final regulations establishing the requirements for the form and manner in which premarket notifications (510(k) submissions) are to be sent to FDA. These regulations also contained provisions governing public disclosure by FDA of the existence of a 510(k) submission.

On November 28, 1990, the President signed into law the SMDA (Pub. L. 101-629) which amended the act. The SMDA requires that a premarket notification under section 510(k) include an adequate summary of any information on safety and effectiveness (510(k) summary) or a statement (510(k) statement) that such information will be made available upon request by any person. Section 12(a) of the SMDA added section 513(i)(3)(B) of the act (21 U.S.C. 360c(i)(3)(B)), which requires FDA to make available to the public any 510(k) summary within 30 days of the issuance of a determination of substantial equivalence. Section 12(b) of the SMDA directs the Secretary to issue regulations establishing the requirements of the summaries under section 513(i)(3)(B) of the act.

The SMDA also requires that persons who submit a premarket notification (submitters) claiming substantial equivalence to a class III device introduced into interstate commerce before December 1, 1990, and for which FDA has not required premarket approval under section 515(b) of the act (21 U.S.C. 360e(b)), certify that they have conducted a reasonable search of all information known or otherwise available to them about the class III device and other similar legally marketed devices (class III certification.) Submitters are also required under section 513(f)(3) of the act to submit a summary (class III summary) of, and a citation to, all adverse safety and effectiveness data associated with the devices being compared. FDA may require the submitter to submit the safety and effectiveness data described in the class III summary.

B. Section 510(k) Summaries

The regulation prescribes the content and format of the summary of safety and effectiveness information required to be submitted under section 513(i)(3) of the act (510(k) summaries). The regulation defines a 510(k) summary as a summary of the safety and effectiveness information contained in the premarket notification submission upon which a determination of substantial equivalence can be based. This safety and effectiveness information includes data supporting a finding of substantial equivalence and all adverse safety and effectiveness data and information on the device. The decision to submit either a 510(k) summary or a 510(k) statement may not be changed once the premarket notification submission has been received by FDA. FDA's decision regarding the existence of substantial equivalence will be based on all the information contained in the 510(k), not only the information contained in the summary. Indeed, FDA may not review all 510(k) summaries due to resource constraints. Submitters are nevertheless required to prepare an adequate summary.

FDA believes that the intent of the requirement that premarket notification submitters provide either a 510(k) summary or a 510(k) statement is to make available to the public information about a device for which a marketing order has been issued and to provide the public with insight into the basis for an equivalence determination. FDA will make publicly available on a regular basis a list of all premarket notification submissions for which substantial equivalence determinations have been made, and information as to whether a 510(k) summary or a 510(k) statement was included. Summaries will be available to the public in accordance with the requirements of section 12(a) of the SMDA. Because 510(k) summaries submitted in premarket notifications are intended, in part, for public disclosure, they are not subject to predisclosure

notification under Executive Order 12600.

The content requirements for 510(k) summaries in this regulation describe the information FDA relies on in determining substantial equivalence. A detailed discussion of FDA's decisionmaking process is contained in FDA's Guidance on the Premarket Notification Review Program. This publication is available from the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ-220), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 800-638-2041 or 301-443-6597. Premarket notification submissions must contain adequate information to permit FDA to conclude whether the new device has the same intended use and technological characteristics as the predicate device. If the device has different technological characteristics, the information in the premarket notification submission must demonstrate that the device is as safe and effective as the predicate device and does not raise any new questions concerning safety and effectiveness. The term different technological characteristics means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the predicate device.

Because the content requirements for a 510(k) summary are different depending on the type of supporting data required in a premarket notification submission, it is important to understand the different types of data that may be submitted. All submissions must contain descriptive data and information sufficient to describe clearly the intended use, physical composition, method of operation, specifications, and performance claims of the new device. Any similar information submitted with respect to the predicate or legally marketed device is also considered descriptive data.

Under certain circumstances, FDA requires performance testing information, i.e., data from bench, animal, or clinical tests, to support an assertion that the device performs according to its description. Generally, FDA will not require performance testing data to support substantial equivalence if there are no significant differences in the technological characteristics of the new device and the predicate or legally marketed device, i.e., the new device involves no new materials, methods of operation, etc., and its descriptive characteristics and precise enough to ensure that the devices will perform comparably if the new device is manufactured according to its description.

In contrast, FDA generally will require performance testing data to establish substantial equivalence if a new device has different technological characteristics than a predicate or legally marketed device, or when the descriptive characteristics of the devices are insufficient to ensure that the devices will perform comparably. In these cases, performance testing data are necessary to demonstrate that the new characteristics of the device do not cause it to perform less safely or less effectively than the legally marketed device to which it is being compared.

The regulations delineating the contents of a 510(k) summary are designed to be sufficiently flexible to permit the summary to be as simple or as complex as the supporting information that it is summarizing. In accordance with § 807.92(a), summaries of premarket notification submissions containing only descriptive information to support equivalence would be required to contain only general information about the device and a summary of the descriptive information respecting safety and effectiveness supporting equivalence. FDA believes that these 510(k) summaries should be brief, generally not exceeding one page.

In contrast, when the determination of substantial equivalence is based on an assessment of performance data, the supporting information is generally more voluminous and more complex. Accordingly, § 807.92(a) and (b) require that the 510(k) summaries for these submissions be more comprehensive, and contain descriptions and analyses of the performance data included in the premarket notification submissions. As a result, FDA expects the 510(k) summaries for these submissions to be lengthier than for submissions containing descriptive information only. FDA reminds 510(k) summary preparers that the 510(k) summary is not intended to be a reproduction of the premarket notification. Rather, it should be a clear and concise discussion of the information respecting safety and effectiveness contained in the submission that supports a determination of substantial equivalence.

In determining whether the new device has the same intended use as a predicate device, FDA assesses any differences in indications for use in terms of the safety and effectiveness questions they may raise. The labeling for a new device need not contain the identical therapeutic or diagnostic statements that appear in the labeling of a predicate device in order for FDA to conclude that the devices have the same intended use. FDA may determine that a new device is substantially equivalent to a predicate device even though the indications may differ in certain respects, provided that these differences do not pose new questions concerning safety or effectiveness that were not posed by the intended use of the predicate device. Ordinarily, FDA relies on descriptive information alone in deciding whether any differences in indications preclude a finding of substantial equivalence. However, where the equivalence determination is based on information obtained from limited testing, the summary should include that information, as required in § 807.92(b).

C. Section 510(k) Statements

In accordance with section 513(i)(1)(B)(3)(A) of the act (21 U.S.C. 360c(i)(B)(3)(A)), in lieu of submitting a 510(k) summary, premarket notification submitters may provide the agency with a 510(k) statement that the submitter will make available information in the premarket notification on safety and effectiveness upon request by any person. The information to be made available includes adverse safety and effectiveness information in the premarket notification submission that supports a finding of substantial equivalence. FDA believes that confidential information concerning patient identifiers, however, would not be required to be disclosed. FDA is adding new § 807.93 to describe the contents of a 510(k) statement.

While the regulations do not contain specific requirements as to how firms should release safety and effectiveness information to requestors, FDA believes that such requests should be filled within 30 days of their receipt. FDA believes that, in most cases, the requirement to provide an adequate summary of information on safety and effectiveness would be satisfied by making available those parts of the premarket notification submission relating to the finding of equivalence, descriptive information, and performance testing results, including detailed information concerning adverse health effects. Because a determination of substantial equivalence is based only on the information contained in a premarket notification, and because the submitter is required to include in its submission all pertinent data in support of its claim of equivalence, FDA believes that the information a submitter is required to furnish in response to a request for information should be taken

only from the information contained in the premarket notification submission. In the case of a dispute over the adequacy of the information released to a requestor by a premarket notification submitter, FDA believes that the entire premarket notification, excluding confidential patient identifiers and other confidential information that is not safety and effectiveness information, should be released. Failure to comply with the commitment made in a 510(k) statement is a prohibited act under section 301(q)(2) of the act (21 U.S.C. 331(q)(2)).

Where a premarket notification submitter elects to provide a statement rather than a summary, the interim rule does not provide for exclusion of trade secret or confidential commercial information that is also considered safety and effectiveness information from the information disclosed by the submitter to any person who requests the information. Earlier informal statements made by FDA officials about section 513(i)(1)(B)(3)(A) of the act contemplated that confidential safety and effectiveness information could be excluded from the information given to requesters. In developing this interim rule, however, FDA found that this position was unsupported by the statute and legislative history. FDA expects that sponsors that do not wish to disclose safety and effectiveness information they regard as confidential are likely to elect to submit summaries instead of 510(k) statements. FDA specifically requests comments on this issue.

II. Class III Summaries and Class III Certification

In accordance with section 4 of the SMDA (21 U.S.C. 360c(f)(3)), new § 807.87(i) is being added to require submitters of premarket notification submissions claiming substantial equivalence to a class III device for which no final regulation requiring premarket approval applications has been issued under section 515(b) of the act to include a summary of and a citation to all adverse safety and effectiveness data on the device and its predicate (class III summary). The section requires the submitter to certify that a reasonable search of all information known or otherwise available on the predicate device has been conducted (class III certification).

A. Summaries

FDA has interpreted the adverse safety and effectiveness data referred to in this section to include the types of safety and effectiveness problems to which that type of class III predicate device is suspectible and the potential causes of such problems. The summary of adverse safety and effectiveness data required for these submissions should be based upon a reasonable search of all information known or otherwise available to the 510(k) submitter about the type of class III predicate or legally marketed device to which the device that is the subject of the premarket notification submission is being compared. FDA does not believe that preparation of such a summary should necessitate original research or speculative forecasting by a 510(k) submitter. Limiting the class III summary and class III certification to adverse safety and effectiveness information known only about the device for which the premarket notification was submitted and a single predicate or legally marketed device is not consistent with Congressional intent of ensuring that potential adverse safety and effectiveness concerns of that type of device are adequately addressed in a premarket notification. This concern particularly applies in situations where there is limited clinical experience with the subject device. FDA is establishing a format for the class III certification in § 807.94.

B. Truthfulness and Accuracy Certification

As a result of an Office of the Inspector General's July 1990 report on internal control of the 510(k) process, FDA is adding new § 807.87(j), requiring persons who submit a premarket notification to certify the truthfulness and accuracy of the submission.

III. Confidentiality of Premarket Notification Submissions

The agency recognizes that the intent to market a device is often considered confidential commercial information because premature disclosure of a firm's marketing plans could provide a competitive advantage to the firm's competitors. This economic reality is reflected in § 807.95(b), which establishes a procedure whereby a submitter may request that FDA hold as confidential a premarket notification submission for a device that is not on the market and for which the intent to market has not been disclosed. In accordance with that section, FDA will treat a premarket notification as confidential if the submitter certifies in writing:

(1) That the submitter considers the intent to market the device to be confidential commercial information,

(2) That neither the submitter nor anyone else has disclosed the intent to market the device to certain enumerated individuals,

(3) That the person will notify the agency if the intent to market the device is disclosed to certain enumerated individuals,

(4) That the submitter has taken precautions to protect the confidentiality of its intention to market a device, and

(5) That the submitter understands that the submission to the government of false information is prohibited, and if FDA agrees that the intent to market the device is confidential commercial information.

FDA believes that § 807.95(b) is affected by the enactment of section 513(i) of the act. As stated above, the summary disclosure requirement in section 513(i)(3)(B) of the act becomes effective only when the agency has issued a determination of substantial equivalence. Therefore, a submitter may continue to request confidentiality in accordance with § 807.95(b), so long as the agency has not yet issued a determination that the device is substantially equivalent to another device.

Section 807.95(c) prescribes the length of time that the agency will protect the confidentiality of a submitter's intent to market a device. In general, when the agency determines that the submitter has complied with the procedures described in § 807.95(b), the agency will protect the confidentiality of the intent to market a device for 90 days from the date of FDA's receipt of the premarket notification submission.

Section 807.95(c) provides three situations in which the period of confidential treatment may be extended for more than 90 days. First, § 807.95(c)(1) allows for an extended period of confidentiality when the agency requests additional information regarding the device. Because it applies to a situation in which a substantial equivalence determination has not yet been made, § 807.95(c)(1) is unaffected by new section 513(i)(3)(B) of the act.

Second, § 807.95(c)(2) allows the agency to hold a premarket notification submission confidential when a decision has been made that the device cannot be marketed without premarket approval or reclassification. In this situation, the agency has, in effect, made a determination that the manufacturer's device is not substantially equivalent to another device. Consequently, the agency believes that this section is consistent with the new amendments and is unaffected by the enactment of section 513(i)(3)(B) of the act.

The third situation, § 807.95(c)(3), requires modification, however. Section 807.95(e)(3) currently allows the submitter to request that the intent to

market a device be held in confidence for more than 90 days when the submitter has reason to believe that the actual marketing of the device may be delayed and the intent to market has not been disclosed by the submitter. Thus, § 807.95(c)(3) would permit extended confidentiality for a premarket notification submission even after FDA has made a determination that the device is substantially equivalent and, consequently, directly conflicts with new section 513(i)(3)(B) of the act. Therefore, the agency has deleted § 807.95(c)(3) and replaced it with a new provision reflecting the summary disclosure requirements mandated by section 513(i)(3)(B) of the act.

The agency has determined that this rule is a rule of "agency organization, procedure, or practice" and, as such, it is exempt from notice and comment under the Administrative Procedure Act (5 U.S.C. 553(a)(2) and (b)(A)). The Commissioner also finds good cause under 5 U.S.C. 553(b)(B) and 21 CFR 10.40(e) to forgo notice and comment as it would be unnecessary and contrary to the public interest to delay implementation of this rule, in as much as it merely implements the plain directives of the statute. As provided in FDA's administrative practices and procedures regulation (21 CFR 10.40(e)), FDA is providing an opportunity for public comment on whether the regulation should be modified or revoked.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Economic Impact

FDA has carefully examined the economic impact of the rule in accordance with the economic requirements of Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354). The agency concludes that the rule is not a major rule as defined in Executive Order 12291. The provisions of the interim final rule, including the codification of the criteria for determination of substantial equivalence, the 510(k) summaries and class III summaries should assist submitters in organizing their submissions by giving submitters a framework for organizing the discussion of substantial equivalence. The regulation may be used as a checklist by submitters whether they submit a summary or a certification. This should result in better submissions and more efficient review. FDA estimates that the annual cost of submitting 510(k) summaries or statements will be $1.135 million and the annual cost of submitting the requested information, if the statement option is chosen, will be $22,000. The total annual cost will be $1.157 million for the 510(k) summary/statement requirements. In addition, FDA estimates that the annual cost of submitting the class III summaries will be $1.2 million. All of these costs will be spread among several thousand marketers in any year. Therefore FDA certifies that the rule will not have a significant impact on a substantial number of small entities as defined in the Regulatory Flexibility Act. A copy of the document supporting this determination is on file at the Dockets Management Branch (address above) and may be seen in that office between 9 a.m. and 4 p.m., Monday through Friday.

This rule itself is not a major rule, however, the cumulative effect of regulations promulgated under the SMDA may result in a major increase in costs for the device industry and/or have associated costs in excess of the $100 million threshold that defines a major rule. FDA specifically requests comments on the need to consider the regulations promulgated under the SMDA together as a major rule.

VI. Paperwork Reduction Act of 1980

This final rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35). The title, description, and respondent description of the information are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: 510(k) Summaries and Statements Under Public Law 101–629—General Requirements.

Description: FDA is issuing a final rule to implement provisions of SMDA regarding the submission of summaries of safety and effectiveness information along with premarket notifications or a certification that the safety and effectiveness information will be made available to any person upon request. The purpose of these changes is to improve the protection of the public health while also reducing the regulatory burden on manufacturers. The existing information collections have been approved under OMB No. 0910–0120.

Description of Respondents: Manufacturers and importers of medical devices.

ESTIMATED ANNUAL BURDEN FOR REPORTING

CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
Summaries 807.87(h)	1,645	1	1,645	23	37,835
Statements 807.87(h)	3,055	1	3,055	.65	1,986
Citations 807.87(i)	500	1	500	42	21,000
Total					60,821

As required by section 3504(h) of the Paperwork Reduction Act of 1980, FDA has submitted a copy of this final rule to OMB for its review of these information collection requirements. Other organizations and individuals desiring to submit comments regarding this burden estimate or any aspects of these information collection requirements, including suggestions for reducing the burden, should direct them to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, OMB, rm. 3208, New Executive Office Bldg., Washington, DC 20503, Attn: Desk Officer for FDA.

List of Subjects in 21 CFR Part 807

Confidential business information, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 807 is amended as follows:

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS OF DEVICES

1. The authority citation for 21 CFR part 807 continues to read as follows:

Authority: Secs. 301, 501, 502, 510, 513, 515, 519, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 360, 360c, 360e, 360i, 371, 374).

2. Section 807.3 is amended by adding new paragraphs (n), (o), (p), and (q) to read as follows:

§ 807.3 Definitions.

* * * * *

(n) *510(k) summary* (summary of safety and effectiveness) means a summary, submitted under section 513(i) of the act, of the safety and effectiveness information contained in a premarket notification submission upon which a determination of substantial equivalence can be based. Safety and effectiveness information refers to safety and effectiveness data and information supporting a finding of substantial equivalence, including all adverse safety and effectiveness information.

(o) *510(k) statement* means a statement made under section 513(i) of the act, asserting that the information in a premarket notification submission regarding safety and effectiveness that supports a finding of substantial equivalence will be made available, upon request, to the public. The information to be made available includes adverse safety and effectiveness information but excludes patient identifiers.

(p) *Class III certification* means a certification that the submitter of the 510(k) has conducted a reasonable search of all known information about the class III device and other similar, legally marketed devices.

(q) *Class III summary* means a summary of the types of safety and effectiveness problems associated with the devices being compared and a citation to the information upon which the summary is based. The summary must be comprehensive and describe the types of problems to which the device is susceptible and the causes of such problems.

3. Section 807.87 is amended by redesignating paragraph (h) as paragraph (k) and by adding new paragraphs (h), (i), and (j) to read as follows:

§ 807.87 Information required in a premarket notification submission.

* * * * *

(h) A 510(k) summary as described in § 807.92 or a 510(k) statement as described in § 807.93.

(i) For submissions claiming substantial equivalence to a device which has been classified into class III under section 513(b) of the act:

(1) Which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990; and

(2) For which on final regulation requiring premarket approval has been issued under section 515(b) of the act, a summary of the types of safety and effectiveness problems associated with the devices being compared and a citation to the information upon which the summary is based (class III summary). The 510(k) submitter shall also certify that a reasonable search of all information known or otherwise available about the class III device and other similar legally marketed devices has been conducted (class III certification), as described in § 807.94. This information does not refer to information that already has been submitted to the Food and Drug Administration (FDA) under section 519 of the act. FDA may require the submission of the adverse safety and effectiveness data described in the class III summary or citation.

(j) A statement that all data and information submitted in the premarket notification is truthful and accurate and that no material fact has been omitted.

* * * * *

4. New §§ 807.92, 807.93, and 807.94 are added to subpart E to read as follows:

§ 807.92 Content and format of a 510(k) summary.

(a) A 510(k) summary shall be in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence. All 510(k) summaries shall contain the following information:

(1) The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;

(2) The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;

(3) An identification of the predicate or legally marketed device or devices to which substantial equivalence is being claimed;

(4) A description of the device that is the subject of the premarket notification submission, including an explanation of how the device functions, the basic scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device such as device design, materials used, and physical properties;

(5) A statement of the intended use of the device, including a general description of the diseases or conditions the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended. If the indication statements are different from those of the predicate or legally marketed device identified in paragraph (a)(3) of this section, the summary shall contain an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device and why the differences do not affect the safety or effectiveness of the device when used as labeled; and

(6) A statement of how the technological characteristics of the device (i.e., design, material, chemical composition, or energy source) compare to those of the predicate or legally marketed device identified in paragraph (a)(3) of this section.

(b) 510(k) summaries for those premarket notification submissions in which a determination of substantial equivalence is based on an assessment of performance data shall contain the following information in addition to the information required by paragraph (a) of this section:

(1) A brief discussion of the nonclinical tests and their results submitted in the premarket notification;

(2) A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety and/or effectiveness data obtained with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence; and

(3) The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is safe, effective, and performs as well as or better than the legally marketed device

identified in paragraph (a)(3) of this section.

(c) The summary should be in a separate section of the submission, beginning on a new page and ending on a page not shared with any other section of the premarket notification submission, and should be clearly identified as a "510(k) summary."

§ 807.93 Format of a 510(k) statement.

A 510(k) statement submitted as part of a premarket notification shall state as follows:

I certify that [name of person required to submit the premarket notification] will make available all information included in this premarket notification on safety and effectiveness that supports a finding of substantial equivalence within 30 days of request by any person. The information I agree to make available does not include confidential patient identifiers.

(This statement should be made in a separate section of the premarket notification submission and should be clearly identified as a 510(k) statement.)

§ 807.94 Format of a class III certification.

A class III certification submitted as part of a premarket notification shall state as follows:

I certify that a reasonable search of all information known or otherwise available to (name of premarket notification submitter) about the types and causes of reported safety and/or effectiveness problems for the (type of device) has been conducted. I further certify that the types of problems to which the (type of device) is susceptible and their potential causes are listed in the attached class III summary, and that this class III summary is complete and accurate.

(This statement should be clearly identified as a class III certification and should be made in the section of the premarket notification submission that includes the class III summary.)

5. Section 807.95 is amended by removing paragraph (c)(3), by redesignating paragraph (d) as paragraph (e), and by adding new paragraph (d) to read as follows:

§ 807.95 Confidentiality of information.

* * * * *

(d) FDA will disclose publicly a premarket notification submitter's summary of the safety and effectiveness data on the device within 30 days of the issuance of a determination that the device is substantially equivalent to another device. Accordingly, even when a manufacturer has complied with the conditions set forth in paragraphs (b) and (c) of this section, confidentiality for a premarket notification submission can not be granted beyond 30 days after FDA issues a determination of equivalency.

* * * * *

Dated: December 6, 1991.

Editorial Note: This document was received by the Office of the Federal Register on April 23, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 92-9797 Filed 4-27-92; 8:45 am]

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federal register

Tuesday
April 28, 1992

Part VII

Environmental Protection Agency

40 CFR Part 52

State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990; Supplemental; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL-4127-1]

State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990; Supplemental

AGENCY: Environmental Protection Agency (EPA).

ACTION: General Preamble for future proposed rulemakings; Appendices.

SUMMARY: The EPA published a General Preamble for the Implementation of title I of the Clean Air Act Amendments of 1990 on April 16, 1992 (57 FR 13498). This document describes EPA's preliminary views on how EPA should interpret various provisions of title I of the Clean Air Act Amendments of 1990, primarily those concerning State implementation plan (SIP) revisions required for nonattainment areas. It serves as advance notice of how EPA generally intends, in subsequent rulemakings, to take action on SIP submissions.

The appendices to the General Preamble were inadvertently omitted. The appendices contain important support materials that are referenced throughout the General Preamble. Therefore, this notice, containing the aforementioned appendices, serves as a supplement to the General Preamble and should be considered as such.

FOR FURTHER INFORMATION CONTACT: Mr. Brock Nicholson, Chief, Policy Development Section, Ozone/CO Programs Branch (MD-15) at (919) 541-5517, for issues related to ozone or carbon monoxide; Mr. Eric Ginsburg at (919) 541-0877, Sulfur Dioxide/Particulate Matter Programs Branch (MD-15), for issues related to sulfur dioxide, particulate matter, or lead; Mr. Gary McCutchen at (919) 541-5592, Permits Programs Branch (MD-15), for issues related to new source review, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; Ms. Paula Van Lare at (202) 260-3450 for issues related to mobile sources, 401 M Street, SW, Washington, DC 20460.

ADDRESSES: The appendices are also in Air Docket A-91-35, at 401 M Street, SW, Washington, DC.

Dated: April 21, 1992.

Michael Shapiro,

Acting Assistant Administrator for Air and Radiation.

Appendix A—Glossary

ACT = alternative control technique
AVO = average vehicle occupancy
BACM = best available control measures
BACT = best available control technology
CAA = Clean Air Act
CAAA = Clean Air Act Amendments
CARB = California Air Resources Board
CEMS = continuous emission monitoring system
CO = carbon monoxide
CPM = condensible particulate matter
CTG = control technique guideline
DOI = Department of the Interior
DOT = Department of Transportation
EKMA = Empirical Kinetic Modeling Approach
ERC = emission reduction credits
ETC = employer transportation coordinator
ETPS = Emission Trading Policy Statement
FIP = Federal Implementation Plan
FMVCP = Federal Motor Vehicle Control Program
FR = **Federal Register**
GVWR = Gross Vehicle Weight Rating
HC = hydrocarbons
I/M = inspection and maintenance
IPP = inventory preparation plan
LAER = lowest achievable emission rate
MMS = Minerals Management Service
MSA/CMSA = metropolitan statistical area/consolidated metropolitan statistical area
NAAQS = national ambient air quality standards
NAS = National Academy of Sciences
NO_2 = Nitrogen dioxide
NO_x = nitrogen oxides
NSPS = new source performance standard
NSR = New Source Review
OCS = outer continental shelf
PSD = prevention of significant deterioration
psi = pounds per square inch
RACM = reasonably available control measures
RACT = reasonably available control technology
RFP = reasonable further progress
RTA = rural transport area
RVP = Reid vapor pressure
SCAQMD = South Coast Air Quality Management District
SO_2 = sulfur dioxide
SIP = State implementation plan
TCM = transportation control measures
TSP = total suspended particulate (matter)
VOC = volatile organic compound
VMT = vehicle miles traveled

Appendix B—Bibliography and Cited References

To obtain copies of OAQPS documents, contact the EPA Library, (919) 541-5514; (FTS) 629-5514. For OMS publications, please contact Mark Wolcott, (313) 668-4219; (FTS) 374-8219.

SIP Inventory Guidance/Requirements

"Procedures for Preparing Emissions Projections," EPA-450/4-91-019, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Research Triangle Park, NC, July 1991.

"Procedures for Emission Inventory Preparation, Volume IV: Mobile Sources," EPA-450/4-81-026d, U.S. Environmental Protection Agency, Office of Mobile Sources, Ann Arbor, MI, July 1991. (also listed below under General Inventory Guidance).

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"Procedures for Estimating and Applying Rule Effectiveness in Post-1987 Base Year Emission Inventories for Ozone and Carbon Monoxide State Implementation Plans," U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Research Triangle Park, NC, June 1989.

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"Procedures for Emission Inventory Preparation," U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Research Triangle Park, NC:

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b. "Volume II: Point Sources," EPA-450/4-81-026b, September 1981.

c. "Volume III: Area Sources," EPA-450/4-81-026c, September 1981.

d. "Volume IV: Mobile Sources," EPA-450/4-81-026d (Revised), July 1981.

e. "Volume V: Bibliography," EPA-450/4-81-026e, September 1981.

Emission Factors/Models

"Personal Computer Version of the Biogenic Emissions Inventory System (PC-BEIS) With User's Guide," EPA-450/4-91-017, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Research Triangle Park, NC, July 1991.

"User's Guide to MOBILE4 (Mobile Source Emission Factor Model)," EPA-AA-TEB-89-01, U.S. Environmental Protection Agency, Office of Mobile Sources, Ann Arbor, MI, February 1989. (Revised version of MOBILE4 and documentation to be completed in July 1991.)

"Surface Impoundment Modeling System (SIMS) Version 2.0 User's Manual," EPA-450/4-90-019a, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Research Triangle Park, NC, September 1990.

"Background Document for Surface Impoundment Modeling System (SIMS) Version 2.0, EPA-450/4-90-019b," U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Research Triangle Park, NC, September 1990.

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"Control of Open Fugitive Dust Sources," EPA-450/3-88-008, September 1988.

"Guidance Document for Residential Wood Combustion Emission Control Measures," EPA-450/2-89-015, September 1989.

"Prescribed Fire Smoke Management Guide," NFES No. 1279, February 1985.

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Memorandum from William Laxton, Director, Technical Support Division, to Regional Air Division Directors, "Guidance for Determining Significant Stationary Sources of Carbon Monoxide," May 13, 1991.

Memorandum from John Seitz, OAQPS to Air Division Director, Regions I-X, "New Source Review (NSR) Program Transitional Guidance," March 11, 1991.

Memorandum from John Calcagni and William Laxton, "Interim Guidance on Emission Limits and Stack Test Methods for Inclusion in PM-10 SIP's," December 24, 1990.

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Memorandum from Joseph Tikvart and Robert Bauman concerning modeling guidelines addressing PM-10, dated July 15, 1990.

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Appendix C1—Available Fugitive Dust Control Measures

Background

The available control measures listed below apply to all fugitive dust sources except those to which only available control technology is applicable (i.e., process fugitive dust associated with stationary sources). Fugitive dust is particulate matter suspended in the air either by mechanical disturbance of the surface material or by wind action blowing across the surface. Mechanical disturbance includes resuspension of particles from vehicles traveling over roadways, parking lots, and other open areas. Wind action includes dust blown off inadequately stabilized open areas. The quantity of fugitive dust emissions is dependent upon several factors such as the size of the source, emission rate, and control efficiency. The Environmental Protection Agency's (EPA) policy is to reduce fugitive dust emissions, with an emphasis on preventing, rather than mitigating, them. For example, past efforts to control emissions from paved roads have usually relied on street cleaning to reduce silt loading. The new approach would put a higher priority on measures to prevent silt from getting on the road surface. Mitigative measures should be reserved for those areas/situations where prevention is not feasible. Technical guidance on fugitive dust control measures is found in *Control of Open Fugitive Dust Sources* (EPA-450/3-88-008 September, 1988).

List of Available Control Measures

1. Pave, vegetate, or chemically stabilize access points where unpaved traffic surfaces adjoin paved roads.

2. Require dust control plans for construction or land clearing projects.

3. Require haul trucks to be covered.

4. Provide for traffic rerouting or rapid clean up of temporary (and not readily preventable) sources of dust on paved roads (water erosion runoff, mud/dirt carryout areas, material spills, skid control sand). Delineate who is responsible for cleanup.

5. Require paving, chemically stabilizing, or otherwise stabilizing permanent unpaved haul roads, and parking or staging areas at commercial, municipal, or industrial facilities.

6. Develop traffic reduction plans for unpaved roads. Use of speed bumps, low speed limits, etc., to encourage use of other (paved) roads.

7. Limit use of recreational vehicles on open land (e.g., confine operations to specific areas, require use permits, outright ban).

8. Require improved material specification for and reduction of usage of skid control sand or salt (e.g., require use of coarse, nonfriable material during snow and ice season).

9. Require curbing and pave or stabilize (chemically or with vegetation) shoulders of paved roads.

10. Pave or chemically stabilize unpaved roads.

11. Pave, vegetate, or chemically stabilize unpaved parking areas.

12. Establish dust control measures for material storage piles.

13. Provide for storm water drainage to prevent water erosion onto paved roads.

14. Require vegetation, chemical stabilization, or other abatement of wind erodible soil, including lands subjected to water mining, abandoned farms, and abandoned construction sites.

15. Rely upon the soil conservation requirements (e.g., conservation plans, conservation reserve) of the Food Security Act to reduce emissions from agricultural operations.

Appendix C2—Available Residential Wood Combustion Control Measures

Background

Wood smoke from residential wood stoves and fireplaces is a significant source of PM-10 pollution in some areas in the western United States that do not attain the PM-10 ambient air quality standards. For example, in some mountain communities, atmospheric inversions can trap wood smoke particulates in valleys and cause PM-10 concentrations to reach levels well in excess of the standards.

The U.S. EPA's new source performance standard (53 FR 5860, February 26, 1988) is a long-term strategy designed to improve the performance of wood burning devices nationwide. The EPA believes that this standard alone, though, may not result in attainment of the PM-10 air quality standards in areas affected by wood smoke. Additional available control measures are listed below. They are intended to (1) reduce emissions from current stoves through inspections, education, and shifting to cleaner stoves or fuel; (2) curtail the use of wood stoves or fireplaces during adverse meteorological conditions; and (3) limit future growth in emissions. Additional guidance on these measures is contained in EPA-450/2-89-015 (September 1989), *Guidance Document for Residential Wood Combustion Emission Control Measures*. Nothing in this document prevents a State implementation plan (SIP) in a moderate PM-10 nonattainment area from containing control measures more stringent than RACM.

List of Available Control Measures

1. Establish an episode curtailment program, including: A curtailment plan; a communication strategy to implement the plan; a surveillance plan (e.g., "windshield" survey, opacity trigger); and enforcement provisions including procedures, penalties, and exemptions). A voluntary program will be deemed reasonable if the area demonstrates attainment.

2. Establish a public information program to inform and educate citizens about stove sizing, installation, proper operation and maintenance, general health risks of wood smoke, new technology stoves, and alternatives to wood heating.

3. Encourage improved performance of woodburning devices by:

—Establishing a program to identify, through opacity observation, deficiencies in stove operation and maintenance. (Under such a program, advice and assistance should be provided to the identified households to help reduce visible emissions from their devices.)

—Providing voluntary dryness certification programs for dealers and/or making free or inexpensive wood moisture checks available to burners.

—Evaluating and encouraging, as appropriate, the accelerated changeover of existing devices to new source performance standard or other clean burning new or existing technology stoves (e.g., hybrid designs, pellet stoves) by such approaches as subsidized stove purchases tax credits, or other incentives.

4. Provide inducements that would lead to reductions in the stove and fireplace population (or use) by:

—Slowing the growth of woodburning devices in new housing units by taxes, installation permit fees, or other disincentives.

—Encouraging a reduction in the number of woodburning devices (i.e., removing or disabling the devices) through tax credits or other incentives.

—Discouraging the resale of used stoves through taxes, fees, or other disincentives.

—Discouraging the availability of free (or very inexpensive) firewood by increasing cutting fees or limiting the cutting season.

Appendix C3—Prescribed Burning Control Measures

Background

Prescribed burning, including silvicultural and agricultural burning, is a contributor to PM-10 nonattainment in some regions. In many cases, well-established smoke management approaches are not being followed, resulting in avoidable air quality problems. The EPA has been working closely with the National Wildfire Coordinating Group (NWCG) to develop appropriate

guidance. The objective is to establish smoke management (SM) programs in these areas which constitute reasonably available control measures (RACM), and reduce population exposure to smoke from prescribed burning, while assuring that resource management goals are met.

States should address emissions from prescribed burning in a manner that balances natural resource, agricultural, and other burning objectives with air quality goals and objectives, by utilizing a smoke management program as described in the NWCG's Prescribed Fire Smoke Management Guide (NFES No. 1279, February 1985) and the Prescribed Fire Plan Guide (NFES No. 1939, August 1986), publications of the Boise (Idaho) Interagency Fire Center.

The scope of a SM program should reflect the specific conditions and requirements of a local area. Existing programs may be adequate in many cases and in other cases may provide a basis for developing a refined program. Smoke management should encourage the cooperative efforts of local, State, Federal, and private land managers. Emphasis should be on conducting burns under an established planning process.

For the purpose of PM-10 SIP development, the term prescribed burning includes all open burning of vegetative matter. This includes both planned ignition and prescribed natural fire. Nothing in a SM program constituting RACM is intended to influence vegetation management or fire suppression practices so as to increase the potential for wildfire to the point that natural resources or public safety are compromised.

The EPA believes it is reasonable that a SM program apply in those moderate PM-10 nonattainment areas where it has been shown, through monitoring, modeling, or other analysis, that prescribed burning can or does contribute to violations of the PM-10 national ambient air quality standards (NAAQS). The SM program should also apply to areas outside of the nonattainment area if it is shown that prescribed burning outside of the nonattainment area can or does contribute to NAAQS violations. The prescribed burning control measures reasonably may be limited only to the season(s) when high ambient PM-10 concentrations occur, if it can be shown that the annual PM-10 NAAQS is not violated. *See* H.R. Rep. No. 490, 101st Cong., 2d Sess. 268-269 (1990).

Source categories (e.g., burning of fencelines, ditch banks, small brush piles, small prescribed natural burns, garden plots) may not be reasonably controlled where their impact is de minimis based on consideration of their collective influence on PM-10 emissions, their duration, season, and proximity to potentially affected populations.

An SM program should consist of at least the following components:

Smoke Dispersion Evaluation

As a minimum, the program should use National Weather Service forecasts or other meteorological analyses to determine when meteorological conditions are favorable or unfavorable for dispersion and transport of smoke (i.e., "burn days," "no burn days").

Burn Planning, Authorization, and Administration

The smoke management program should provide a process (e.g., telephone call-in) for receiving burn requests, evaluating requests and granting approval for burns. Approval of a burn should be based on an evaluation of the airshed's capacity/capability to disperse emissions on allowable burn days so that the cumulative emissions from all burns and other sources in the airshed will not cause or contribute to violations of the PM-10 NAAQS. The approval to burn on a burn day should be equitably divided among all categories of burners requesting approval to burn while accommodating the "incentives" specified elsewhere in this policy.

Requirements for Ensuring Burner Qualifications

Voluntary training in smoke management techniques should be reasonably available for all burners. The program should include incentives for burners who complete the voluntary training (e.g., priority for approval to burn on "burn days").

Public Education and Awareness

Information programs on the nature of and reasons for smoke management should be periodically presented to the public (e.g., public service announcements, newspaper articles).

Surveillance and Enforcement

The SM program should rely on routine PM-10 monitoring, and/or modeling supplemented by periodic visual assessments of the effectiveness of the dispersion evaluation program. The existing PM-10 monitoring network should be evaluated for its ability to provide information on the effectiveness of the SM program as applied to burning conducted in and near the nonattainment area. The network should be modified as appropriate. The program should also provide a process for documenting and following up on public complaints and should provide for and levy fines against burners who violate any of its mandatory requirements.

Emission Inventories and Emission Efforts

States should develop and maintain an emission inventory for prescribed burning and all burns should be categorized as to their purpose. Documentation of the size, date, purpose, and emission reduction measures used should be submitted following each large burn. Emission reduction techniques (e.g., mass ignition, rapid mop-up) should be encouraged and incentives (e.g., priority for approval to burn on "burn days") should be offered for demonstrated emission reduction efforts, including the use of alternatives to burning, provided that such incentives can be utilized without compromising resource management objectives.

State Oversight

The relationship of the State air pollution agency with other State agencies to which management of the SM program may have been delegated will need to be determined on a State-by-State basis. Nevertheless, State rules and regulations should be enacted in such a manner that all provisions of the SM program are enforceable by the State through its State implementation plan. Generally, memorandums of understanding should be utilized to clearly specify working relationships among agencies.

Appendix C4—RACT Determinations for Stationary Sources

Background

Congress has for the second time in amending the Clean Air Act (Act) specifically required that reasonable available control technology (RACT) be applied to existing stationary sources in nonattainment areas. In section 172(b)(3) of the Act, as amended in 1977, Congress specified that nonattainment area plans were to "require, * * *, reasonable further progress * * * including such reduction in emissions from existing sources in the area as may be obtained through the adoption, at a minimum, of reasonably available control technology." Thus, RACT was required in SIP's developed for areas that were designated nonattainment for total suspended particulate matter. Now, in section 172(c)(1) of the Clean Air Act, as amended by the Clean Air Act Amendments of 1990 (Nonattainment Plan Provisions—In General), Congress again requires that nonattainment area plans provide for "* * * such reductions in emissions from existing sources in the (nonattainment) area as may be obtained through the adoption, at a minimum, of reasonably available control technology." Thus, RACT is now required for PM-10 nonattainment area SIP's.

The EPA recommends that the RACT for a particular source continues to be determined on a case-by-case basis considering the technological and economic feasibility of reducing emissions from that source (through process changes or add-on control technology). The following technological and economic parameters should be considered in determining RACT for a particular source.

Technological Feasibility

The technological feasibility of applying an emission reduction method to a particular source should consider the source's process and operating procedures, raw materials, physical plant layout, and any other environmental impacts such as water pollution, waste disposal, and energy requirements. The process, operating procedures, and raw materials used by a source can affect the feasibility of implementing process changes that reduce emissions and the selection of add-on emission control equipment. The operation of and longevity of control equipment can be significantly influenced by the raw materials used and the process to which it is applied. The feasibility of modifying processes or applying control equipment is also influenced by the physical layout of the particular plant. The space available in which to implement such changes may limit the choices and will also affect the costs of control.

Reducing air emissions may not justify adversely affecting other resources by increasing pollution of bodies of water, creating additional solid waste disposal

problems or creating excessive energy demands. (An otherwise available PM-10 control technology may not be reasonable if these other environmental impacts cannot reasonably be mitigated.) For analytic purposes, a State may consider a PM-10 control measure technologically infeasible if, considering the availability (and cost) of mitigative adverse impacts of that control on other pollution media, the control would not, in the State's reasoned judgment, provide a net environmental benefit. In many instances, however, PM-10 control technologies have known energy penalties and adverse effects on other media, but such effects and the cost of their mitigation are also known and have been borne by owners of existing sources in numerous cases. Such well-established adverse effects and their costs are normal and assumed to be reasonable and should not, in most cases, justify nonuse of the PM-10 control technology. The costs of preventing adverse water, solid waste and energy impacts will also influence the economic feasibility of the PM-10 control technology.

Alternative approaches to reducing emissions of particulate matter including PM-10 are discussed in Control Techniques for Particulate Emissions from Stationary Sources—Volume I (EPA-450/3-81-005a) and Volume II (EPA-450/3-81-005b), September 1982. The design, operation and maintenance of general particulate matter control systems such as mechanical collectors, electrostatic precipitators, fabric filters, and wet scrubbers are discussed in Volume I. The collection efficiency of each system is discussed as a function of particle size. Information is also presented regarding energy and environmental considerations and procedures for estimating costs of particulate matter control equipment. The emission characteristics and control technologies applicable to specific source categories are discussed in Volume II. Secondary environmental impacts are also discussed.

Additional sources of information on control technology are background information documents for new source performance standards and Identification, Assessment, and Control of Fugitive Particulate Emissions, EPA-600/8-86-023, August 1986.

In some instances, control technologies more modern or more advanced than those described in the documents referenced may exist. In such cases, the State's RACT analysis for a source should consider such available technology.

Economic Feasibility

Economic feasibility considers the cost of reducing emissions and the difference in costs between the particular source and other similar sources that have implemented emission reduction. As discussed above, EPA presumes that it is reasonable for similar sources to bear similar costs of emission reductions. Economic feasibility rests very little on the ability of a particular source to "afford" to reduce emissions to the level of similar sources. Less efficient sources would be rewarded by having to bear lower emission reduction costs if affordability were given high consideration. Rather, economic feasibility for RACT purposes is largely determined by evidence that other sources in a source category have in fact applied the control technology in question.

The capital costs, annualized costs, and cost effectiveness of an emission reduction technology should be considered in determining its economic feasibility. The OAQPS Control Cost Manual, Fourth Edition, EPA-450/3-90-006, January 1990, describes procedures for determining these costs. The above costs should be determined for all technologically feasible emission reduction options.

States may give substantial weight to cost effectiveness in evaluating the economic feasibility of an emission reduction technology. The cost effectiveness of a technology is its annualized cost ($/year) divided by the amount of PM-10 emission reduction (i.e., tons/year) which yields a cost per amount of emission reduction ($/ton). Cost effectiveness provides a value for each emission reduction option that is comparable with other options and other facilities.

If a company contends that it cannot afford the technology that appears to be RACT for that source or group of sources, the claim should be supported with such information as the impact on:

1. Fixed and variable production costs ($/unit),
2. Product supply and demand elasticity,
3. Product prices (cost absorption vs. cost pass-through),
4. Expected costs incurred by competitors,
5. Company profits, and
6. Employment.

If a company contends that available control technology is not affordable and would lead to closing the facility, the costs of closure should be considered. Closure may incur costs for demolition, relocation, severance pay, etc.

Appendix D

United States Environmental Protection Agency, Office of Air Quality Planning and Standards, Research Triangle Park, North Carolina 27711.

March 11, 1991.

Memorandum

Subject: New Source Review (NSR) Program Transitional Guidance.

From: John S. Seitz, Director, Office of Air Quality Planning and Standards (MD-10).

To: Addressees.

The Clean Air Act Amendments of 1990 (1990 Amendments) make numerous changes to the NSR requirements of the prevention of significant deterioration (PSD) and nonattainment area programs. The 1990 Amendments create new and expanded nonattainment areas, extend PSD coverage to current Class I area boundaries, and mandate a PSD exemption for certain hazardous air pollutants. The Environment Protection Agency (EPA) intends to propose by September of this year a regulatory package that will implement these and other changes to the NSR provisions. Final adoption of these revised regulations is projected for August 1992. In the interim period between passage of the 1990 Amendments and adoption of the Agency's final regulations, EPA expects that numerous issues regarding the 1990 Amendments will arise. This memorandum sets forth the Agency's position on the most important of these transitional issues involving the NSR program.

This guidance document does not supersede existing State regulations or approved State implementation plans. However, in some cases, it calls upon States to implement their NSR programs in a manner consistent with provisions of the 1990 Amendments that are applicable immediately and with the requirements that flow directly from these provisions. Nonetheless, the policies set out in this transition memorandum are intended solely as guidance and do not represent final Agency action. They are not ripe for judicial review for this reason. Moreover, they are not intended, nor can they be relied upon, to create any rights enforceable by any party in litigation with the United States. The EPA officials may decide to follow the guidance provided in this memorandum, or to act at variance with the guidance, based on an analysis of specific circumstances. The Agency also may change this guidance at any time without public notice.

The Regional Offices should send this guidance document to their States. Questions from States and applicants concerning specific issues and cases should be directed to the appropriate EPA Regional Office. If you have any general questions, please contact Mr. Michael Sewell of the New Source Review Section at FTS 629-0873 or (919) 541-0873.

Attachment

Addressees

Director, Air, Pesticides, and Toxics Management Division, Regions I, IV, and VI

Director, Air and Waste Management Division, Region II

Director, Air Management Division, Regions III and IX

Director, Air and Radiation Division, Region V

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Corrections to Original Document: Two errors in the document as issued on March 11, 1991 have been corrected in this copy. On page 2 on the last line, "CFC 112" is changed to correctly read "CFC 113". On page 8 in item 4, the cite "Section 172(b)" is changed to correctly read "Section 173(b)".

New Source Review (NSR) Transitional Guidance

Toxics and National Emissions Standards for Hazardous Air Pollutants (NESHAPS) Issues

1. Section 112 Hazardous Air Pollutants are No Longer Considered Regulated Pollutants

Under Prevention of Significant Deterioration (PSD), but NESHAPS Still Apply.

Under the 1977 Amendments to the Clean Air Act (Act) and regulations issued thereunder, the PSD requirements of the Act apply to all "major" new sources and "major" modifications, i.e., those exceeding certain annual tonnage thresholds (see 40 CFR 52.21(b)(1)(i) and (b)(2)(i)). Typically, new sources and modifications become subject to PSD because they exceed the specified tonnage threshold for a criteria pollutant, i.e., a pollutant for which a national ambient air quality standard (NAAQS) has been established under section 109 of the Act. Once a new source or modification is subject to PSD, the PSD requirements apply to every pollutant subject to regulation under the Act that is emitted in "significant" quantities (or, in the case of a major modification, for which there is a significant net emissions increase) (see 40 CFR 52.21(b)(23) and (i)(2)). Under the 1977 Amendments, best available control technology (BACT) and other PSD requirements apply not only to emissions of criteria pollutants but also to emissions of pollutants regulated under other provisions of the Act, such as section 111 or 112. This regulatory structure was altered by the 1990 Amendments.

Title III of the 1990 Amendments added a new section 112(b)(6) that excludes the hazardous air pollutants listed in section 112(b)(1) of the revised Act (as well as any pollutants that may be added to the list) from the PSD (and other) requirements of Part C. Thus, because they are on the initial Title III hazardous air pollutants list, the following pollutants, which had been regulated under PSD because they were covered by the section 112 NESHAPS or section 111 new source performance standards (NSPS) program, are now exempt from Federal PSD applicability:

- Arsenic
- Asbestos
- Benzene (including benzene from gasoline)
- Beryllium
- Hydrogen sulfide (H_2S)
- Mercury
- Radionuclides (including radon and polonium)
- Vinyl chloride

The Title III exemption applies to final Federal PSD permits (i.e., those issued in final form and for which administrative appeals, if any, under 40 CFR 124.19 have been exhausted) issued on or after the date of enactment of the 1990 Amendments (November 15, 1990). For Federal PSD permit applications now under review by either an EPA Regional Office or a delegated State, PSD permit requirements do not apply to the pollutants exempted by Title III. For Federal PSD permits containing PSD requirements for the pollutants exempted by Title III issued on or after November 15, 1990, the permittee may request a revision (e.g., removal of a BACT limit for benzene) to their PSD permit to reflect the Title III exemption from Federal PSD applicability.

Note that pursuant to section 116 and the preservation clause in section 112(d)(7) of the amended Act, States with an approved PSD program may continue to regulate the Title III hazardous air pollutants now exempted from Federal PSD by section 112(b)(6) if the State PSD regulations provide an independent basis to do so. These State rules would remain in effect unless a State revised them to provide similar exemptions. Additionally, the Title III pollutants continue to be subject to any other applicable State and Federal rules; the exclusion is only for Part C rules.

Finally, section 112(q) retains existing NESHAPS regulations by specifying that any standard under section 112 in effect prior to the date of enactment of the 1990 Amendments shall remain in force and effect after such date unless modified as provided in the amended section. Therefore, the requirements of 40 CFR 61.05 to 61.08, including preconstruction permitting requirements, for new and modified sources subject to existing NESHAPS regulations are still applicable.

In summary, the pollutants currently regulated under the Act as of March 1991 that are still subject to Federal PSD review and permitting requirements are:

- Carbon monoxide
- Nitrogen oxides
- Sulfur dioxide
- Particulate matter and PH-10
- Ozone (volatile organic compounds)
- Lead (elemental)
- Fluorides
- Sulfuric acid mist
- Total reduced sulfur compounds (including H_2S)
- CFC's 11, 12, 113, 114, 115
- Halons 1211, 1301, 2402
- Municipal waste combustor (MWC) acid gases, MWC metals and MWC organics

2. Hazardous Air Pollutants that are Regulated as One Component of a More General Pollutant Under Other Provisions of the Clean Air Act are Still Regulated.

Any hazardous air pollutants listed in section 112(b)(1) which are regulated as constituents of a more general pollutant listed under section 108 of the Act are still subject to PSD as part of the more general pollutant, despite the exemption in Title III. For example, volatile organic compounds (VOC's) (a term which includes benzene, vinyl chloride, methanol, toluene, methyl ethyl ketone, and thousands of other compounds) are still regulated as VOC's (but not as individual pollutants such as benzene, etc.) under the PSD regulations because these pollutants are ozone precursors, not because they are air toxics. Also, particulates (including lead compounds and asbestos) are still regulated as particulates (both PM-10 and particulate matter) under the PSD regulations. Lead compounds are exempt from Federal PSD by Title III, but the elemental lead portion of lead compounds (as tested for in 40 CFR part 60, appendix A, Method 12) is still considered a criteria pollutant subject to the lead NAAQS and still regulated under PSD.

3. Toxic Effect of Unregulated Pollutants Still Considered in BACT Analysis.

Based on the remand decision on June 3, 1986 by the EPA Administrator in *North County Resource Recovery Associates* (PSD Appeal No. 85-2), the impact on emissions of other pollutants, including unregulated pollutants, must be taken into account in determining BACT for a regulated pollutant. When evaluating control technologies and their associated emissions limits, combustion practices, and related permit terms and conditions in a BACT proposal, the applicant must consider the environmental impacts of all pollutants not regulated by PSD. Once a project is subject to BACT due to the emission of nonexempted pollutants, the BACT analysis should therefore consider all pollutants, including Title III hazardous air pollutants previously subject to PSD, in determining which control strategy is best.

PSD Class I Boundary Issues

1. PSD Applicability Coverage Changes as Class I Area Boundaries Change

Sections 162(a) and 164(a) of the amended Act specify that the boundaries of areas designated as Class I must now conform to all boundary changes at such parks and wilderness areas made since August 7, 1977 and any changes that may occur in the future. The EPA does not believe that Congress intended to create the turmoil which would occur if this redesignation required the modification of permits issued between August 7, 1977 and November 15, 1990, or the resubmission and reevaluation of complete permit applications submitted prior to enactment of the 1990 Amendments. Thus, for this reason, applications considered complete prior to November 15, 1990 should be processed as submitted without regard to the new Class I area boundaries. Exceptions to this general policy are in the area of increment consumption and air quality related values (including visibility), as discussed below.

For an applicant who submitted a complete PSD application prior to November 15, 1990, if all other PSD requirements are met, a permit may be issued based on the Class I analysis as submitted in the application, unless the reviewing authority finds, on a case-by-case basis, that additional analysis is needed from the applicant to address suspected adverse impacts or increment consumption problems due to the expanded boundaries of the Class I areas. Any existing increment violations in the new boundaries of Class I areas must be remedied through a SIP revision pursuant to 40 CFR 51.166(a)(3).

The PSD applications not considered complete before November 15, 1990 must consider the impact of both existing sources and the new or modified source on the Class I areas as defined by the 1990 Amendments. Thus, the complete application must consider the impacts on the entire Class I area based upon the boundaries in existence of the date of submittal of a complete application; as before, if a Class I boundary changes before the permit is issued, the reviewing authority may find, on a case-by-case basis, that additional analysis is needed from the applicant to address suspected adverse impacts or increment consumption problems due to expanded Class I Area boundaries.

NSR Nonattainment Issues

1. NSR Construction Permit Requirements in Nonattainment Areas

In many States, the existing approved Part D permit program by its terms covers all designated nonattainment areas in the State.

so a Part D permit program will automatically apply to the new and expanded nonattainment areas which are established under provisions of Title I of the 1990 Amendments. Thus, until new rules are adopted for these new or expanded nonattainment areas, States should apply the requirements of their existing approved Part D permit program. However, in other States, a Part D program may be limited to specified areas and does not apply to new or expanded areas. In these cases, States must implement a transitional permitting program until their existing Part D programs are revised to meet the requirements of the 1990 Amendments and expanded to cover all nonattainment areas in the State. Otherwise, both the goals of part D and Congress' intent in creating new or expanded nonattainment areas will be frustrated.

The EPA regulations already provide for these new or expanded designated nonattainment areas because the Emission Offset Interpretations Ruling (40 CFR part 51, appendix S) governs permits to construct between the date of designation and the date an approved Part D plan is made applicable to the new nonattainment area (see 40 CFR 52.24(k)). Until a State's new Part D plan is approved by EPA, if a State wishes to issue a permit for a major stationary source or major modification in a new or expanded designated nonattainment area, the State should comply with the requirements of appendix S. Among other things, appendix S requires a major source seeking to locate in a nonattainment area to (1) meet the lowest achievable emission rate for such source, (2) provide offsets from existing sources in the area, and (3) show that the offsets will provide a positive net air quality benefit (see 40 CFR part 51, appendix S, section IV.A). The EPA believes that in order to carry out the intent of appendix S, offsets should be required for sources in all categories and in all instances should be calculated on a tons per year basis (see 40 CFR part 51, appendix S, section IV.C).

Of course, neither appendix S nor the existing NSR rules incorporate the NSR changes mandated by Title I of the 1990 Amendments such as lower source applicability thresholds, increased emissions offset ratios, new definitions of major stationary source, and (for ozone nonattainment areas) requirements for nitrogen oxides (NOx) control and NOx emissions offsets. However, the 1990 Amendments require States to submit to EPA new NSR permit program rules for ozone nonattainment areas by November 15, 1992; for PM-10 nonattainment areas by June 30, 1992; and for most carbon monoxide (CO) nonattainment areas no later than 3 years from the date of the nonattainment designation. The EPA interprets this as an expression of congressional intent not to mandate that States adhere to the more stringent Title I NSR requirements in nonattainment areas during the time provided for State implementation plan (SIP) development. Thus, for NSR permitting purposes in nonattainment areas, the new NSR requirements in Title I are not in effect until the States, as required by the Act, adopt NSR permit program rules to implement the Title I provisions. In addition, EPA encourages any State having adequate authority for early implementation of the NSR changes to do so as soon as possible.

If States fail to submit to EPA the new NSR permit program rules for nonattainment areas by the deadlines in the amended Act, EPA intends to impose in these nonattainment areas a Federal implementation plan (FIP) embodying such requirements. Currently, EPA intends to propose revised NSR regulations at 40 CFR part 52 that would implement the new Title I NSR requirements under a FIP in a State if that State's revised NSR rules to implement Title I are not submitted in approvable form to EPA and made effective within the State by the deadlines established by the 1990 Amendments.

The area designation in effect on the date of *permit issuance* by the reviewing agency determines which regulations (Part C or Part D) apply to that permit. In other words, the PSD permit regulations apply to pollutants for which the area is designated as attainment or unclassifiable, and the NSR nonattainment permit regulations apply to pollutants for which the area is designated nonattainment (see 40 CFR 51.166(i) (3) and (5); and 40 CFR 52.21(i) (3) and (5)). Under these regulations, a PSD permit for a pollutant cannot be issued in an area that is designated nonattainment for that pollutant. For the situation where a source receives a PSD or other permit prior to the date the area is designated as nonattainment, the permit remains in effect as long as the source commences construction within 18 months after the date of nonattainment designation of the area, does not discontinue construction for more than 18 months, and completes construction within a reasonable time (see 40 CFR 52.24 (g) and (k)). Although the PSD regulations provide for extension of these deadlines, no extension would be appropriate where the area has been designated as nonattainment following permit issuance. Accordingly, if any of these construction provisions are not met, the PSD permit or other permit will not be extended, and the source (if subject to the nonattainment provisions) must obtain a nonattainment permit prior to commencing (or continuing) construction.

The 1990 Amendments create some new and expanded nonattainment areas by operation of law. Other nonattainment area changes are expected as the States and EPA complete the designation process prescribed in amended section 107(d). Because of these provisions, the dates areas switch from attainment to nonattainment for NSR purposes vary by pollutant. However, except for the two instances where the Amendments create changes by operation of law, the new designations and expanded boundaries will not be effective for NSR purposes until EPA promulgates the changes. The promulgations will be announced in the **Federal Register**.

Congress created new PM-10 nonattainment areas through designations that became effective upon enactment of the 1990 Amendments on November 15, 1990 (see section 107(d)(4)(B)). Specifically, Congress designated Group I areas and areas where violations of the PM-10 NAAQS had occurred prior to January 1, 1989 as nonattainment. The EPA published a list of these PM-10 areas in a **Federal Register** notice (see 55 FR 45799, October 31, 1990; see also 52 FR 29383, August 7, 1987). The EPA plans to publish a notice in the **Federal Register** listing these areas as nonattainment in the near future, but they are already considered nonattainment areas as of November 15, 1990.

Similarly, the 1990 Amendments expand by operation of law some CO and ozone nonattainment areas. However, these changes did not become effective with passage but rather on December 30, 1990. The specifics are as follows:

> Section 107(d)(4)(A)(iv) of the amended Act provides that, with the exception explained below ozone and CO nonattainment areas located within metropolitan statistical areas (MSA) and consolidated metropolitan statistical areas (CMSA) which are classified as serious, severe, or extreme for ozone or as serious for CO are automatically expanded to include the entire MSA or CMSA. This expansion became effective by operation of law 45 days after enactment unless the Governor submitted a notice by this deadline of the State's intent to seek a modification of the expanded boundaries pursuant to the procedures set forth in section 107(d)(4)(A)(v). So if a State did not provide this notice, the nonattainment boundaries of all serious, severe, and extreme ozone nonattainment areas in the State and all serious CO areas in the State expanded to include the entire MSA or CMSA on December 30, 1990. If a State did provide timely notice, the Administrator has up to 14 months from enactment to resolve the State's challenge. Until EPA promulgates a resolution of the State's challenge, the old boundaries remain in effect.

Except for these two cases where new or expanded boundaries have been created by operation of law, nonattainment area changes will not be considered effective until the changes are promulgated by the EPA. As to most new areas or expansions of previously-designated nonattainment areas, this will occur 240 days after enactment (see section 107(d)(4)(A) (i) and (ii)). Newly-created ozone and CO nonattainment areas will be considered part of a designated nonattainment area for NSR purposes at the time of promulgation.

2. Status of Construction Bans

Pursuant to section 110(n)(3), an existing construction ban that was imposed due to the absence of approved Part D NSR rules remains in effect until a revised NSR SIP is approved. Existing construction bans imposed due to disapproval of primary sulfur dioxide NAAQS attainment plans also remain in effect. A **Federal Register** notice will be published soon announcing the status of construction bans in general and also lifting specific bans where appropriate. Should a construction ban be lifted in any area designated as nonattainment, and the area lacks an approved Part D NSR rule, the State should meet the requirements of 40 CFR part 51, appendix S, in issuing permits to

major new sources or major modifications prior to the adoption of NSR rules meeting the requirements of the 1990 Amendments.

3. Federal Implementation Plans Remain in Effect

The NSR permitting program in an existing FIP remains in effect until a SIP is approved or a revised FIP is adopted.

4. Use of Previously-Approved Growth Allowances Is Prohibited

Section 173(b) invalidates growth allowances in existing SIP's in areas that received a SIP call prior to enactment of the 1990 Amendments, or that receive one thereafter. For NSR permits issued on or after November 15, 1990, previously-approved growth allowances cannot be used in these areas. Construction permits cannot be issued in SIP-call areas under existing EPA-approved Part D programs to the extent that such permits rely on previously-approved growth allowances. Case-by-case emission offsets must be obtained for any such permits, and other existing Part D requirements must be met.

5. Existing NSR Permitting Rules Continue To Apply in the Northeast Ozone Transport Region (NOTR)

The 1990 Amendments establish a single ozone transport region comprised of the States of Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, and the CMSA that includes the District of Columbia and part of the State of Virginia. For this transport region, including all attainment areas within its boundaries, new section 184(b)(2) specifies that any stationary source that emits or has the potential to emit at least 50 tons per year of VOC's shall be considered a major stationary source and subject to the requirements which would be applicable to major stationary sources if the area were classified as a moderate ozone nonattainment area. For NSR purposes, the requirements of section 184(b)(2) are not in effect in a State until the State submits a new or revised SIP that includes the requirements (or EPA imposes a FIP implementing those requirements). A State in the NOTR has until November 15, 1992 to submit to EPA the new or revised NSR rules addressing the new requirements.

Appendix E

I. Introduction

The EPA is issuing this CTG document under section 182(b) of the Clean Air Act, as amended. Under section 182(b), States must develop RACT rules for sources "covered by a CTG document issued by the Administrator between November 15, 1990 and the date of attainment." The State must submit these RACT rules "within the period set forth by the Administrator in issuing the relevant CTG document." One type of "CTG document" is a CTG; a CTG is a technical document that sets forth a presumptive level of RACT controls for a source category. The Act provides that EPA must issue eleven CTG's by November 15, 1993. In addition, the Act specifically requires the Agency to prepare CTG's for aerospace coatings and ship building and repair within the same timeframe.

This document is not a technical CTG, but rather a second type of CTG document—a document that lists the eleven CTG's EPA anticipates publishing in accordance with section 183(a) and establishes time tables for submittal of RACT rules for sources that are not ultimately covered by a CTG issued by November 15, 1993. The EPA believes that it is necessary to issue this document at this time so that States will be able to determine which sources and source categories fit within the RACT rule submittal requirement for sources that EPA expects to be covered by a post-enactment CTG.

II. List of Eleven CTG's

The EPA plans to issue the following CTG's in accordance with section 183(a).

1. Synthetic organic chemical manufacturing industry (SOCMI) distillation;
2. SOCMI reactors;
3. Wood furniture;
4. Plastic parts coating (business machines);
5. Plastic parts coating (other);
6. Offset lithography;
7. Industrial wastewater;
8. Autobody refinishing;
9. SOCMI batch processing;
10. Volatile organic liquid storage tanks; and
11. Clean up solvents.

III. Authority

Under section 182(b)(2), States must adopt RACT rules for three general groups of sources: (A) Those covered by a post-enactment CTG document; (b) those covered by a pre-enactment CTG; (c) "all other major stationary sources of VOC's." Section 182(b)(2) also establishes the timing for State submittal and source implementation of RACT rules for these three groups. For sources covered by a post-enactment CTG document, the State must submit RACT rules within the period established in the relevant CTG document. For the other two groups, the Act provides specific dates for submittal, November 15, 1992, and implementation, no later than May 31, 1995.

Alone, subparagraphs (A), (B) and (C) seem to set forth three distinct groups of sources. However, the submittal dates under the second portion of the provision potentially could blur the line between these three groups if EPA does not issue before November 15, 1992, a CTG document covering all sources for which it plans to issue a CTG under section 183(a). At that time, States would need to submit RACT rules for all other major stationary sources—those for which neither a pre-enactment CTG nor a post-enactment CTG document had been issued.

The EPA's obligation to issue the eleven CTG's does not ripen until November 15, 1993, and EPA does not anticipate issuing all of these CTG's before November 15, 1992. Therefore, to the extent EPA does not issue a CTG document before November 15, 1992, States would be required to submit non-CTG RACT rules for sources that could in the future be covered by a CTG. In addition, at the time the CTG document was issued, the State could then be required to submit a new rule, consistent with the CTG document, thereby duplicating its earlier effort.

In order to relieve the States from being required to duplicate rules and to relieve sources from potentially being subject to two different requirements within a short period, EPA is issuing this CTG document to retain the sharp distinction between the three different groups in subparagraphs (A), (B), and (C). If a State believes that one of the eleven CTG's listed in Section II will cover a particular major source, the State should follow the timing provisions of Section IV, below for submittal of a rule applicable to that source. The State should identify those sources in its November 15, 1992 RACT submittal.

IV. Time Table

The EPA is establishing the following general time table for States to submit RACT rules for sources that it identifies in a November 15, 1992 submittal as being a source covered by a post-enactment CTG document.

(1) on November 15, 1992, the State must submit a list of major stationary sources that it anticipates will be subject to one of the CTG's listed in Section II, which EPA plans to issue by November 15, 1993.

(2) For those major sources on the list submitted by the State in the 1992 submittal that are not covered by a CTG that EPA has issued by November 15, 1993, the State must submit a RACT rule by November 15, 1994 that requires implementation of RACT by May 15, 1995.

(3) For sources covered by a CTG issued under section 183(a) and for which the State has not, by the date of such issuance, adopted an approvable RACT rule, the State must submit a RACT rule in accordance with the time schedule set forth in the relevant CTG.

(4) For sources subject to a RACT rule that the State adopted and EPA approved under section 182(b)(2) prior to EPA's issuance of an applicable CTG, EPA will work with the State to determine whether the existing rule should be revised once a CTG has been issued that would apply to that source.

[FR Doc. 92-9866 Filed 4-27-92; 8:45 am]

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LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

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102d Congress, 2nd Session, 1992

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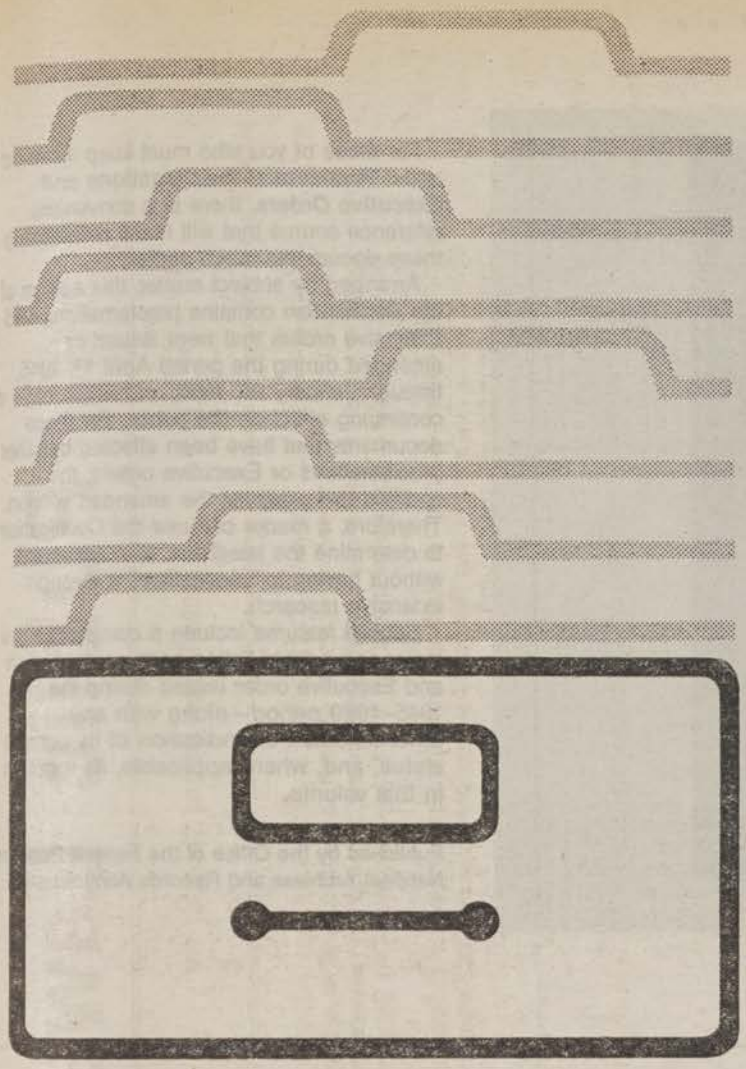

Guide to Record Retention Requirements

in the Code of Federal Regulations (CFR)

GUIDE: Revised January 1, 1989
SUPPLEMENT: Revised January 1, 1991

The GUIDE and the SUPPLEMENT should be used together. This useful reference tool, compiled from agency regulations, is designed to assist anyone with Federal recordkeeping obligations.

The various abstracts in the GUIDE tell the user (1) what records must be kept, (2) who must keep them, and (3) how long they must be kept.

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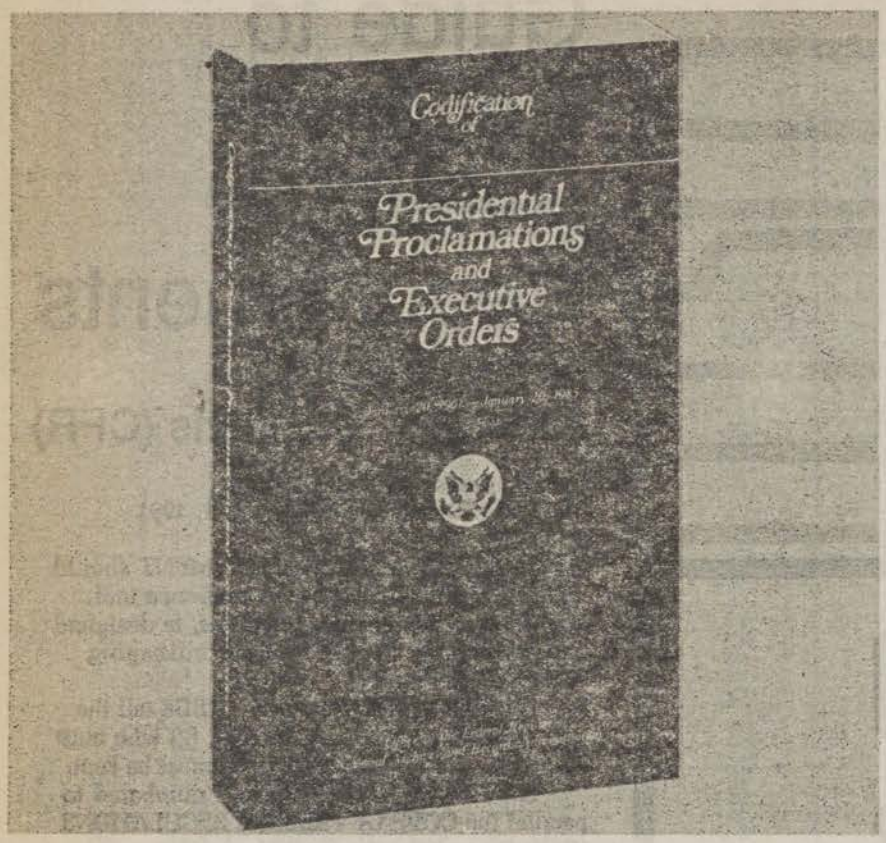

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