The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

Sikorsky Aircraft Corporation: Docket No. 96–SW–29–AD.

Applicability: Model S–61 A, D, E, L, N, NM, R, and V helicopters, with main rotor shaft (shaft), part number (P/N) S6135–20640–001, S6135–20640–002, or S6137–23040–001, installed, certificated in any category.

Note 1: This AD applies to each helicopter identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (d) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any helicopter from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To detect a fatigue crack in the shaft, that could result in shaft structural failure, loss of power to the main rotor, and subsequent loss of control of the helicopter, accomplish the following:

(a) Within the next 30 calendar days or 240 hours time-in-service (TIS) after the effective date of this AD, whichever occurs first, determine if the shaft has been used in repetitive external lift (REL) operations. REL operation is defined as operation during which the average number of external lifts equals or exceeds six per flight hour for any 250 hour TIS period during the main gearbox overhaul interval. An external lift is defined as a flight cycle in which an external load is picked up, the helicopter is repositioned (through flight or hover), and the helicopter hovers and releases the load and departs or lands and departs. Record the total number of hours TIS during which external lifts have been conducted, as well as the number of external lifts conducted during each hour, on the component log card or equivalent record. If the number of external lifts cannot be determined, assume 6 external lifts were conducted during each hour TIS in which external lifts were conducted. If the hours TIS of external lift operations cannot be determined, assume REL operations were conducted.

(b) For shafts used in REL operations, within the next 1,000 hours TIS after the effective date of this AD, conduct a non-destructive inspection (NDI) for cracks in the shaft in accordance with the Overhaul Manual. If a crack is discovered in a shaft, remove the shaft and replace it with an airworthy shaft. Mark the removed airworthy shafts and the replacement shafts in accordance with the Accomplishment Instructions in paragraphs 2E and 2F of Sikorsky Aircraft Corporation ASB No. 61B35–68, dated July 19, 1996. Once a shaft has been designated and marked as an REL shaft, it is life-limited accordingly for the remainder of that shaft's airworthy service life.

(c) Retire all shafts that have been used in REL operations as follows:

(1) Shafts that have been modified in accordance with Sikorsky Customer Service Notice 6135–10, dated March 18, 1987, and Sikorsky ASB No. 61B35–53, dated December 2, 1981 (modified REL shafts), must be removed from service on or before attaining 2,000 hours TIS.

(2) Shafts that have not been modified in accordance with Sikorsky Customer Service Notice 6135–10, dated March 18, 1987, and Sikorsky ASB No. 61B35–53, dated December 2, 1981 (unmodified REL shafts), must be removed from service on or before attaining 1,500 hours TIS.

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Boston Aircraft Certification Office. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Boston Aircraft Certification Office.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Boston Aircraft Certification Office.

(e) This AD revises the Limitations section of the maintenance manual by establishing new retirement lives of 1,500 hours TIS for unmodified REL shafts and 2,000 hours TIS for modified REL shafts.

(f) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be accomplished.

Issued in Fort Worth, Texas, on September 12, 1997.

Eric Bries,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 97–24795 Filed 9–17–97; 8:45 am]

BILLING CODE 4910–13–U

SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404 and 416

RIN 0960–AE74

Federal Old-Age, Survivors, and Disability Insurance Benefits; Supplemental Security Income for the Aged, Blind, and Disabled; Organization and Procedures; Application of Circuit Court Law

AGENCY: Social Security Administration (SSA).

ACTION: Proposed rules.

SUMMARY: These proposed regulations would revise the current regulations governing how we apply holdings of the United States Courts of Appeals that we determine conflict with our interpretation of the Social Security Act or regulations in adjudicating claims under title II and title XVI of the Social Security Act (the Act). The regulations explain the new goal we have adopted to ensure that Acquiescence Rulings (ARs) are developed and issued promptly and the new procedures we are implementing to identify cases pending in the administrative process which might be affected by ARs.

DATES: To be sure your comments are considered, we must have them no later than November 17, 1997.

ADDRESSES: Comments should be submitted in writing to the Commissioner of Social Security, P.O. Box 1585, Baltimore, Maryland 21235, sent by telefax to (410) 966–2830, sent by E-mail to ''regulations@ssa.gov,'' or delivered to the Division of Regulations and Rulings, Social Security Administration, 3-B–1 Operations Building, 6401 Security Boulevard, Baltimore, MD 21235, between 8:00 a.m. and 4:30 p.m. on regular business days. Comments may be inspected during these same hours by making arrangements with the contact person shown below.

FOR FURTHER INFORMATION CONTACT: Harry J. Short, Legal Assistant, Division of Regulations and Rulings, Social Security Administration, 6401 Security Boulevard, Baltimore MD 21235, (410) 965–6243 for information about these rules. For information on eligibility or claiming benefits, call our national toll free number, 1–800–772–1213.

SUPPLEMENTARY INFORMATION: On January 11, 1990, (55 FR 1012) we published final regulations to implement a revised policy for applying circuit court holdings that conflict with our interpretation of the Act or regulations to subsequent claims within that circuit involving the same issue.

Under those regulations, which are set out at 20 CFR 404.985 and 416.1485, we prepare Acquiescence Rulings which explain the circuit court holdings and provide binding guidance to adjudicators on how to apply the holding to subsequent claims within the circuit involving the same issue. Those regulations reflected the agency's decision in 1985 to abandon its prior policy of applying conflicting circuit court holdings only to the named party or parties to the decision, rather than to other cases pending before an Administrative Law Judge or the Appeals Council involving the same issue or issues. The 1990 regulations expanded the 1985 policy decision to apply an AR to all levels of adjudication, as appropriate.

After the 1990 regulations were adopted, allegations that the agency refused to acquiesce in circuit court decisions with holdings in conflict with our interpretation of the Act or regulations declined dramatically. A major goal of the 1990 regulations has been achieved because the circuit courts have found virtually no cause to cite the agency for failing to adhere to circuit court precedent.

On July 2, 1996, we issued Social Security Ruling 96–1p (61 FR 34470) reaffirming the rules established in the 1990 regulations. Since that time, we have reviewed our rules and our implementing procedures to determine what changes could be instituted to further improve the acquiescence process. Our review has led us to conclude that we should reaffirm an important principle regarding the impact of litigation on claims adjudication and, through these final regulations, amend the 1990 regulations in two significant respects.

The Role of Litigation in the Policymaking Process

Our review indicated that it is important to reaffirm the principle that our goal in administering our programs is to have uniform, national program standards. Our procedures, which provide for acquiescence within the circuit when a circuit court issues a decision containing a holding which conflicts with our interpretation of the Act or regulations, result in differing policies in different sections of the country. This situation is not desirable and ordinarily should not, if possible, continue indefinitely.

Therefore, we wish to make it clear that generally ARs are temporary measures. When we receive a circuit court decision containing a holding which conflicts with our interpretation of the Act or regulations, we consider whether the rule at issue should be changed on a nationwide basis to conform to the court's holding. If we continue to believe that our interpretation of the statute or regulations at issue is correct and we seek further judicial review of the circuit court's decision, we will stay further development of the AR until the judicial review process runs its course. If our assessment shows that we should change our rules and adopt a circuit court's holding nationwide, we will, at the time we publish the AR, have determined the steps necessary to do so. This may require changing our regulations or rulings; it may also require seeking a clarifying legislative change to the Act. In this case, however, we would proceed to issue an AR since adopting the rules nationwide inevitably requires a significant period of time.

Similarly, if our assessment is that our rules are correct but we are unable to resolve the matter by seeking further judicial review, we will issue an AR and at the time we publish the AR have determined the appropriate steps to attempt to address the issue which was the subject of the circuit court's holding. This may mean issuing clarifying regulations or seeking legislation. There are certain instances when an issue cannot be resolved, such as a constitutional issue which the Supreme Court chooses not to review and, therefore, an AR may remain in effect.

Although our goal to have uniform national standards is implicit in the current regulations, we are including in this preamble, an explicit statement of our commitment to maintaining a uniform nationwide system of rules and regulations. In addition to making minor editorial corrections to the current regulations, these proposed rules would amend the regulations in two substantive areas, as follow:

Establishing a Timeliness Goal for Issuing Acquiescence Rulings

A common criticism regarding the current process involves the length of time it takes for SSA to prepare and issue an AR. As a result, we have reassessed our procedures and have decided that we will release an AR for publication in the **Federal Register** no later than 120 days from the time we receive a precedential circuit court decision for which the AR is being issued, unless further judicial review of that decision is pending. We propose to add new sections 404.985(b)(1) and 416.1485(b)(1) so that the public is fully informed of this timeframe.

Identifying Pending Claims Which May Be Affected by an AR

When we published the 1990 regulations, we noted that a number of commenters on the 1988 proposed regulations (53 FR 46628 (November 18, 1988)) urged that we take action to identify and list pending claims that might be affected by an AR. In the response to that comment, we stated:

> As a matter of operational necessity, some time will always elapse between the date of a court decision and the time that we could notify all adjudicators to begin listing cases which might be affected by its holding. Thus, a substantial number of cases would not be listed for later readjudication. The process which these comments suggest presumes instantaneous, comprehensive identification of all cases, which operationally we cannot accomplish. Therefore, despite the fact that requiring claimants to seek readjudication does require some action on their part, we have concluded that this is the most efficient and effective way to proceed and have not adopted these comments in the final regulations.

(55 FR 1012, 1013). The basic facts noted in our response remain valid. Despite improved technology, it is still operationally impossible for us to identify all pending claims that might be affected by an AR. However, we have reassessed this situation and have now decided that it would be a significant benefit to claimants if we were to act as expeditiously as possible to identify pending claims that might be affected by an AR, even though we will not be able to identify all such claims.

Therefore, as described in the proposed new sections 404.985(b)(3) and 416.1485(b)(3), we are implementing the following procedures. As soon as possible after we receive a circuit court decision that we find may contain a holding that conflicts with our interpretation of the Act or regulations, we will develop and provide our adjudicators with criteria that they will use to identify pending claims we are deciding within the relevant circuit that might be affected, if we subsequently determine that an AR is required. If an AR is subsequently released, a notice will be sent informing the claimant in these cases that might be affected by the AR that an AR has been issued that might affect the claim. The notice to the claimant will also explain the procedures for obtaining a readjudication of the claim under the AR. If we develop criteria and begin identifying cases but subsequently determine that an AR is not required, the notices will not be sent.

We will notify adjudicators of the appropriate criteria to be used to identify cases no later than 10 days after

we receive a circuit court decision that we determine may contain a holding which conflicts with our interpretation of the Act or regulations. Although we believe that the new procedure to identify pending claims within the relevant circuit that might be affected will greatly reduce the number of claimants who would have to learn of the issuance of the AR through the **Federal Register** publication of it or otherwise, the new procedure will not capture everyone. For this reason, we have retained the readjudication procedure in sections 404.985(b)(2) and 416.1485(b)(2) to ensure the protection of all claimants. Additionally, if a claimant or an adjudicator brings to our attention that a claim could potentially be affected by a circuit court decision that might become the subject of an AR, we will consider identifying that case pending a decision as to whether an AR is necessary in the circuit court decision in question.

Electronic Version

The electronic version of this document is available on the Federal Bulletin Board (FBB) at 9:00 a.m. on the date of publication in the **Federal Register**. To download the file, modem dial (202) 512–1387. The FBB instructions will explain how to download the file and the fee. This file is in WordPerfect and will remain on the FBB during the comment period.

Regulatory Procedures

Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and determined that these rules do not meet the criteria for a significant regulatory action under Executive Order 12866. Thus, they are not subject to OMB review.

Regulatory Flexibility Act

We certify that these regulations will not have a significant economic impact on a substantial number of small entities because these rules affect only individuals. Therefore, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

These proposed rules contain reporting requirements in Part 404, section 404.985(b)(2) and 416.1485(b)(2). As required by 42 U.S.C. section 3507, as amended by section 2 of the Paperwork Reduction Act of 1995, we will submit a copy to the Office of Management and Budget for its review.

The regulation sections cited above allow claimants to request application of the published Acquiescence Ruling to a prior determination or decision. Claimants must demonstrate that the application of the Acquiescence Ruling could change the prior determination or decision. Claimants may do so by submitting a statement. If the claimant can so demonstrate, the information will be used to readjudicate the claim. Thus, claimants, whose determinations or decisions on their claims may be affected by the Acquiescence Ruling, may continue to make submissions to the Agency regarding such claims.

We estimate that the public reporting burden will be 17 minutes per response for between 0 and 50,000 respondents depending on the characteristics of the individual AR, resulting in up to 7083.33 burden hours per AR. We estimate there will be 3 to 4 ARs per year. If you have any comments or suggestions on this estimate, write to OMB and SSA at the following addresses:

Office of Management and Budget, OIRA, Attn: Laura Oliven, Room 10230, New Executive Office Building, Washington, D.C. 20503.

Social Security Administration, DCFAM. Attn: Nicholas E. Tagliareni, 1–A–21 Operations Building, 6401 Security Blvd., Baltimore, MD 21235.

In addition to your comments on the accuracy of the Agency's burden estimate, we are soliciting comments on the need for the information; its practical utility; ways to enhance its quality, utility and clarity; and on ways to minimize the time it takes for claimants to request application of the Acquiescence Ruling to the prior determination, including the use of automated collection techniques or other forms of information technology.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.002, Social Security-Retirement Insurance; 96.003, Social Security-Special Benefits for Persons Aged 72 and Over; 96.004, Social Security-Survivors Insurance; 96.005, Special Benefits for Disabled Coal Miners; 96.006, Supplemental Security Income)

List of Subjects

20 CFR Part 404

Administrative practice and procedure, Death benefits, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Supplemental Security Income (SSI), Reporting and recordkeeping requirements.

Dated: September 11, 1997.

John J. Callahan,

Acting Commissioner of Social Security.

For the reasons set out in the preamble, subpart J of part 404 and subpart N of part 416 of chapter III of title 20 of the Code of Federal Regulations are proposed to be amended as set forth below.

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

1. The authority citation for subpart J of part 404 continues to read as follows:

Authority: Secs. 201(j), 205 (a), (b), (d)–(h), and (j), 221, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 401(j), 405 (a), (b), (d)–(h), and (j), 421, 425, and 902(a)(5)); 31 U.S.C. 3720A; sec. 5, Pub. L. 97–455, 96 Stat. 2500 (42 U.S.C. 405 note); secs. 5, 6 (c)–(e), and 15, Pub. L. 98–460, 98 Stat. 1802 (42 U.S.C. 421 note).

2. Section 404.985 is revised to read as follows:

§ 404.985 Application of circuit court law.

The procedures which follow apply to administrative determinations or decisions on claims involving the application of circuit court law.

(a) *General.* We will apply a holding in a United States Court of Appeals decision that we determine conflicts with our interpretation of a provision of the Social Security Act or regulations unless the Government seeks further judicial review of that decision or we relitigate the issue presented in the decision in accordance with paragraphs (c) and (d) of this section. We will apply the holding to claims at all levels of administrative adjudication within the applicable circuit unless the holding, by its nature, applies only at certain levels of adjudication.

(b) *Issuance of an Acquiescence Ruling.* When we determine that a United States Court of Appeals holding conflicts with our interpretation of a provision of the Social Security Act or regulations and the Government does not seek further judicial review or is unsuccessful on further review, we will issue a Social Security Acquiescence Ruling. The Acquiescence Ruling will describe the administrative case and the court decision, identify the issue(s) involved, and explain how we will apply the holding, including, as necessary, how the holding relates to other decisions within the applicable circuit. These Acquiescence Rulings will generally be effective on the date of their publication in the **Federal Register**

and will apply to all determinations and decisions made on or after that date unless an Acquiescence Ruling is rescinded as stated in paragraph (e) of this section. The process we will use when issuing an Acquiescence Ruling follows:

(1) We will release an Acquiescence Ruling for publication in the **Federal Register** for any precedential circuit court decision that we determine contains a holding that conflicts with SSA's interpretation of a provision of the Social Security Act or regulations no later than 120 days from the receipt of the court's decision. This timeframe will not apply when we decide to seek further judicial review of the circuit court decision or when coordination with the Department of Justice and/or other Federal agencies makes this timeframe no longer feasible.

(2) If we make a determination or decision on your claim between the date of a circuit court decision and the date we publish an Acquiescence Ruling, you may request application of the published Acquiescence Ruling to the prior determination or decision. You must demonstrate that application of the Acquiescence Ruling could change the prior determination or decision in your case. You may demonstrate this by submitting a statement that cites the Acquiescence Ruling and indicates what finding or statement in the prior determination or decision conflicts with the Acquiescence Ruling. If you can so demonstrate, we will readjudicate the claim at the level at which it was last adjudicated in accordance with the Acquiescence Ruling. Any readjudication will be limited to consideration of the issue(s) covered by the Acquiescence Ruling and any new determination or decision on readjudication will be subject to administrative and judicial review in accordance with this subpart. Our denial of a request for readjudication will not be subject to further administrative or judicial review. If you file a request for readjudication within the 60-day appeal period and we deny that request, we shall extend the time to file an appeal on the merits of the claim to 60 days after the date that we deny the request for readjudication.

(3) After we receive a precedential circuit court decision and determine that an Acquiescence Ruling may be required, we will begin to identify those claims that are pending before us within the circuit and that might be subject to a readjudication if an Acquiescence Ruling is subsequently issued. When an Acquiescence Ruling is published, we will send notices to those individuals whose cases we have identified which may be affected by the Acquiescence Ruling. The notice will provide information about the Acquiescence Ruling and the right to request a readjudication under that Acquiescence Ruling, as described in paragraph (b)(2) of this section. It is not necessary for an individual to receive a notice in order to request application of an Acquiescence Ruling to his or her claim, as described in paragraph (b)(2) of this section.

(c) *Relitigation of court's holding after publication of an Acquiescence Ruling.* After we have published an Acquiescence Ruling to reflect a holding of a United States Court of Appeals on an issue, we may decide under certain conditions to relitigate that issue within the same circuit. We will relitigate only when the conditions specified in paragraphs (c) (2) and (3) of this section are met, and, in general, one of the events specified in paragraph (c)(1) of this section occurs.

(1) Activating events:

(i) An action by both Houses of Congress indicates that a court case on which an Acquiescence Ruling was based was decided inconsistently with congressional intent, such as may be expressed in a joint resolution, an appropriations restriction, or enactment of legislation which affects a closely analogous body of law;

(ii) A statement in a majority opinion of the same circuit indicates that the court might no longer follow its previous decision if a particular issue were presented again;

(iii) Subsequent circuit court precedent in other circuits supports our interpretation of the Social Security Act or regulations on the issue(s) in question; or

(iv) A subsequent Supreme Court decision presents a reasonable legal basis for questioning a circuit court holding upon which we base an Acquiescence Ruling.

(2) The General Counsel of the Social Security Administration, after consulting with the Department of Justice, concurs that relitigation of an issue and application of our interpretation of the Social Security Act or regulations at the administrative level within the circuit would be appropriate.

(3) We publish a notice in the **Federal Register** that we intend to relitigate an Acquiescence Ruling issue and that we will apply our interpretation of the Social Security Act or regulations at the administrative level within the circuit to claims selected for relitigation. The notice will explain why we made this decision.

(d) *Notice of relitigation.* When we decide to relitigate an issue, we will provide a notice explaining our action to all affected claimants. In adjudicating claims subject to relitigation, decisionmakers throughout the SSA administrative review process will apply our interpretation of the Social Security Act and regulations, but will also state in written determinations or decisions how the claims would have been decided under the circuit standard. Claims not subject to relitigation will continue to be decided under the Acquiescence Ruling in accordance with the circuit standard. So that affected claimants can be readily identified and any subsequent decision of the circuit court or the Supreme Court can be implemented quickly and efficiently, we will maintain a listing of all claimants who receive this notice and will provide them with the relief ordered by the court.

(e) *Rescission of an Acquiescence Ruling.* We will rescind as obsolete an Acquiescence Ruling and apply our interpretation of the Social Security Act or regulations by publishing a notice in the **Federal Register** when any of the following events occurs:

(1) The Supreme Court overrules or limits a circuit court holding that was the basis of an Acquiescence Ruling;

(2) A circuit court overrules or limits itself on an issue that was the basis of an Acquiescence Ruling;

(3) A Federal law is enacted that removes the basis for the holding in a decision of a circuit court that was the subject of an Acquiescence Ruling; or

(4) We subsequently clarify, modify or revoke the regulation or ruling that was the subject of a circuit court holding that we determined conflicts with our interpretation of the Social Security Act or regulations, or we subsequently publish a new regulation(s) addressing an issue(s) not previously included in our regulations when that issue(s) was the subject of a circuit court holding that conflicted with our interpretation of the Social Security Act or regulations and that holding was not compelled by the statute or Constitution.

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

1. The authority citation for subpart N continues to read as follows:

Authority: Sec. 702(a)(5), 1631, and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1383, and 1383b).

2. Section 416.1485 is revised to read as follows:

§ 416.1485 Application of circuit court law.

The procedures which follow apply to administrative determinations or

decisions on claims involving the application of circuit court law.

(a) *General.* We will apply a holding in a United States Court of Appeals decision that we determine conflicts with our interpretation of a provision of the Social Security Act or regulations unless the Government seeks further judicial review of that decision or we relitigate the issue presented in the decision in accordance with paragraphs (c) and (d) of this section. We will apply the holding to claims at all levels of administrative adjudication within the applicable circuit unless the holding, by its nature, applies only at certain levels of adjudication.

(b) *Issuance of an Acquiescence Ruling.* When we determine that a United States Court of Appeals holding conflicts with our interpretation of a provision of the Social Security Act or regulations and the Government does not seek further judicial review or is unsuccessful on further review, we will issue a Social Security Acquiescence Ruling. The Acquiescence Ruling will describe the administrative case and the court decision, identify the issue(s) involved, and explain how we will apply the holding, including, as necessary, how the holding relates to other decisions within the applicable circuit. These Acquiescence Rulings will generally be effective on the date of their publication in the **Federal Register** and will apply to all determinations and decisions made on or after that date unless an Acquiescence Ruling is rescinded as stated in paragraph (e) of this section. The process we will use when issuing an Acquiescence Ruling follows:

(1) We will release an Acquiescence Ruling for publication in the **Federal Register** for any precedential circuit court decision that we determine contains a holding that conflicts with SSA's interpretation of a provision of the Social Security Act or regulations no later than 120 days from the receipt of the court's decision. This timeframe will not apply when we decide to seek further judicial review of the circuit court decision or when coordination with the Department of Justice and/or other Federal agencies makes this timeframe no longer feasible.

(2) If we make a determination or decision on your claim between the date of a circuit court decision and the date we publish an Acquiescence Ruling, you may request application of the published Acquiescence Ruling to the prior determination or decision. You must demonstrate that application of the Acquiescence Ruling could change the prior determination or decision in your case. You may demonstrate this by submitting a statement that cites the Acquiescence Ruling and indicates what finding or statement in the prior determination or decision conflicts with the Acquiescence Ruling. If you can so demonstrate, we will readjudicate the claim at the level at which it was last adjudicated in accordance with the Acquiescence Ruling. Any readjudication will be limited to consideration of the issue(s) covered by the Acquiescence Ruling and any new determination or decision on readjudication will be subject to administrative and judicial review in accordance with this subpart. Our denial of a request for readjudication will not be subject to further administrative or judicial review. If you file a request for readjudication within the 60-day appeal period and we deny that request, we shall extend the time to file an appeal on the merits of the claim to 60 days after the date that we deny the request for readjudication.

(3) After we receive a precedential circuit court decision and determine that an Acquiescence Ruling may be required, we will begin to identify those claims that are pending before us within the circuit and that might be subject to a readjudication if an Acquiescence Ruling is subsequently issued. When an Acquiescence Ruling is published, we will send notices to those individuals whose cases we have identified which may be affected by the Acquiescence Ruling. The notice will provide information about the Acquiescence Ruling and the right to request a readjudication under that Acquiescence Ruling, as described in paragraph (b)(2) of this section. It is not necessary for an individual to receive a notice in order to request application of an Acquiescence Ruling to his or her claim, as described in paragraph (b)(2) of this section.

(c) *Relitigation of court's holding after publication of an Acquiescence Ruling.* After we have published an Acquiescence Ruling to reflect a holding of a United States Court of Appeals on an issue, we may decide under certain conditions to relitigate that issue within the same circuit. We will relitigate only when the conditions specified in paragraphs (c) (2) and (3) of this section are met, and, in general, one of the events specified in paragraph (c)(1) of this section occurs.

(1) Activating events:

(i) An action by both Houses of Congress indicates that a court case on which an Acquiescence Ruling was based was decided inconsistently with congressional intent, such as may be expressed in a joint resolution, an appropriations restriction, or enactment of legislation which affects a closely analogous body of law;

(ii) A statement in a majority opinion of the same circuit indicates that the court might no longer follow its previous decision if a particular issue were presented again;

(iii) Subsequent circuit court precedent in other circuits supports our interpretation of the Social Security Act or regulations on the issue(s) in question; or

(iv) A subsequent Supreme Court decision presents a reasonable legal basis for questioning a circuit court holding upon which we base an Acquiescence Ruling.

(2) The General Counsel of the Social Security Administration, after consulting with the Department of Justice, concurs that relitigation of an issue and application of our interpretation of the Social Security Act or regulations at the administrative level within the circuit would be appropriate.

(3) We publish a notice in the **Federal Register** that we intend to relitigate an Acquiescence Ruling issue and that we will apply our interpretation of the Social Security Act or regulations at the administrative level within the circuit to claims selected for relitigation. The notice will explain why we made this decision.

(d) *Notice of relitigation.* When we decide to relitigate an issue, we will provide a notice explaining our action to all affected claimants. In adjudicating claims subject to relitigation, decisionmakers throughout the SSA administrative review process will apply our interpretation of the Social Security Act and regulations, but will also state in written determinations or decisions how the claims would have been decided under the circuit standard. Claims not subject to relitigation will continue to be decided under the Acquiescence Ruling in accordance with the circuit standard. So that affected claimants can be readily identified and any subsequent decision of the circuit court or the Supreme Court can be implemented quickly and efficiently, we will maintain a listing of all claimants who receive this notice and will provide them with the relief ordered by the court.

(e) *Rescission of an Acquiescence Ruling.* We will rescind as obsolete an Acquiescence Ruling and apply our interpretation of the Social Security Act or regulations by publishing a notice in the **Federal Register** when any of the following events occurs:

(1) The Supreme Court overrules or limits a circuit court holding that was the basis of an Acquiescence Ruling;

(2) A circuit court overrules or limits itself on an issue that was the basis of an Acquiescence Ruling;

(3) A Federal law is enacted that removes the basis for the holding in a decision of a circuit court that was the subject of an Acquiescence Ruling; or

(4) We subsequently clarify, modify or revoke the regulation or ruling that was the subject of a circuit court holding that we determined conflicts with our interpretation of the Social Security Act or regulations, or we subsequently publish a new regulation(s) addressing an issue(s) not previously included in our regulations when that issue(s) was the subject of a circuit court holding that conflicted with our interpretation of the Social Security Act or regulations and that holding was not compelled by the statute or Constitution.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 111

[Docket No. 95N–0304]

RIN 0901–AA59

Dietary Supplements Containing Ephedrine Alkaloids; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening from September 18, 1997, to December 2, 1997, the comment period on the proposed rule on dietary supplements containing ephedrine alkaloids that was published in the **Federal Register** of June 4, 1997 (62 FR 30678). This action is being taken to provide a renewed opportunity for public comment after the agency has rectified a number of inadvertent omissions from the administrative record. FDA is also providing an opportunity for comment on adverse event reports (AER's) that FDA has received since January 1997 and on new analytical data that FDA is adding to the administrative record. Finally, FDA is reopening the comment period in response to several requests for extensions of the comment period to permit interested persons to submit new scientific data.

DATES: Written comments by December 2, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Margaret C. Binzer, Center for Food Safety and Applied Nutrition (HFS–456), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–401–9859, FAX 202–260–8957 or E-mail ''MBinzer @Bangate.fda.gov''.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 4, 1997, FDA published a proposed rule regarding the formulation and labeling of dietary supplements containing ephedrine alkaloids. FDA proposed this rule in response to serious illnesses and injuries, including multiple deaths, associated with the use of dietary supplement products that contain ephedrine alkaloids and in response to the agency's investigations and analyses of these illnesses and injuries. Interested persons were given until August 18, 1997, to comment on the proposal.

In the **Federal Register** of August 20, 1997 (62 FR 44247), FDA announced that it would reopen the comment period for the proposed rule because the agency had identified a number of inadvertent omissions (i.e., missing pages in several of the AER's and other minor problems) in the administrative record. FDA has reviewed each of the AER's to rectify these omissions, which included: Missing product labels or labeling, affidavits from consumers or health care professionals, investigator followup reports, and individual pages from medical records. FDA has recopied each of the AER files and placed them on display at the Dockets Management Branch. Any followup materials that the agency received after the AER's were made part of the administrative record for this rulemaking in June 1997 are now included in the corresponding AER. For convenience to the users of the administrative record, the agency has also organized the duplicate AER files to make it easier to locate them in the record.

As of January 1997, FDA had received over 800 reports of adverse events associated with the use of more than 100 different dietary supplements that contained, or were suspected of containing, ephedrine alkaloids. Since that time, FDA has continued to receive additional AER's associated with the use of these products. FDA is adding the AER's that it received between January and August 1997 to supplement the administrative record. These documents are filed in the administrative record under the title: ''AER's Associated with the Use of Dietary Supplements Containing Ephedrine Alkaloids that FDA has Received Since the Preparation of the Docket Submission of January 17, 1997.''

Since the time that the proposal was published, FDA has received the results of chemical analyses for several of the dietary supplement products associated with AER's. When an adverse event appears to be clinically significant, FDA routinely requests from the consumer a sample of the remaining portion of the product related to the AER and has its laboratories analyze the sample. These analytical results provide supplementary data on levels of ephedrine alkaloids in the dietary supplements. FDA is adding these analytical results to the administrative record. A summary of these analytical results are filed in the administrative record under the title: ''Analytical Results of Ephedrine Alkaloid-Containing Dietary Supplements Associated With Adverse Events, August 1997.'' These documents will be placed on display in the Dockets Management Branch along with the rest of the administrative record that FDA has compiled to date.

In addition, FDA has received several requests for extensions of the comment period. These requests stated as grounds for an extension, among other things, that there is a need for additional time to review the clinical data and other information in the administrative record and to submit new scientific data to the agency. Several requests were for extensions of 180 days.

Having carefully considered these requests and given the fact that it has added material to the administrative record, the agency has decided to reopen the comment period until December 2, 1997. The reopening of the comment period will provide interested persons with a significant amount of additional time to evaluate all the information in the administrative record that underlies the proposal that FDA published in June 1997 and to formulate any comments that they deem appropriate. The agency particularly encourages small businesses to take advantage of this additional opportunity to participate in the regulatory process.

Because of the serious and significant adverse events associated with the use of dietary supplements containing ephedrine alkaloids, FDA is concerned about the adverse impact that a prolonged comment period may have on the public health. For this reason, the agency decided not to grant the requests for an additional comment period longer than 75 days. The agency's decision to reopen the comment period for 75 days balances the needs of interested persons