DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 10

[Docket No. 98N–0361]

Administrative Practices and Procedures; Internal Review of Decisions

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations governing the internal review of agency decisions by inserting a statement that sponsors, applicants, or manufacturers of drugs (including human drugs, animal drugs, and human biologics) or devices may request review of a scientific controversy by an appropriate scientific advisory panel, or advisory committee. This amendment implements the ''Dispute Resolution'' provision of the Food and Drug Administration Modernization Act (FDAMA). This document is intended to clarify that sponsors, applicants, or manufacturers of drugs, or devices may request review of scientific controversies by an appropriate scientific advisory panel or advisory committee.

EFFECTIVE DATE: December 18, 1998.

FOR FURTHER INFORMATION CONTACT:

For information regarding this final rule: Suzanne M. O'Shea, Office of the Chief Mediator and Ombudsman (HF–7), Food and Drug Administration, 5600 Fishers Lane, rm. 14–105, Rockville, MD 20857, 301–827–3390.

For information about requesting section 404 of FDAMA (21 U.S.C. 360bbb-1) reviews in the Center for Biologics Evaluation and Research: Rebecca A. Devine, Associate Director for Policy, Center for Biologics Evaluation and Research (HFM–001), Food and Drug Administration, 1401 Rockville Pike, suite 200 North, Rockville, MD 20852–1448, 301–827–0373, or

For information about requesting section 404 reviews in the Center for Devices and Radiological Health: James G. Norman, Senior Policy Analyst-Acting Ombudsman, Center for Devices and Radiological Health (HFZ–001), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–4690, or

For information about requesting section 404 reviews in the Center for Drug Evaluation and Research: Murray M. Lumpkin, Deputy Director for Review Management, Center for Drug Evaluation and Research (HFD–002), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400, or

For information about requesting section 404 reviews in the Center for Veterinary Medicine: Marcia K. Larkins, Ombudsman, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0137.

SUPPLEMENTARY INFORMATION:

I. Background

On November 21, 1997, President Clinton signed into law FDAMA (Pub. L. 105–115). Section 404 of FDAMA amends the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*) by adding a new provision, Dispute Resolution (section 562 of the act (21 U.S.C. 360bbb-1)). The dispute resolution provision states that:

> If, regarding an obligation concerning drugs or devices under this Act or section 351 of the Public Health Service Act, there is a scientific controversy between the Secretary and a person who is a sponsor, applicant, or manufacturer and no specific provision of the Act involved, including a regulation promulgated under such Act, provides a right of review of the matter in controversy, the Secretary shall, by regulation, establish a procedure under which such sponsor, applicant, or manufacturer may request a review of such controversy, including a review by an appropriate scientific advisory panel described in section 505(n) or an advisory committee described in section 515(g)(2)(B). Any such review shall take place in a timely manner. The Secretary shall promulgate such regulations within 1 year after the date of the enactment of the Food and Drug Administration Modernization Act of 1997.

Section 404 of FDAMA requires FDA to create a procedure to resolve scientific controversies if no other mechanism for resolving the dispute is contained in the act or regulations issued under the act. The act and agency regulations currently set forth many varied processes that regulated industry may use to resolve disputes under certain specified circumstances. In addition to these specific processes, § 10.75 (21 CFR 10.75) provides that any interested person may obtain review of any agency decision by raising the matter with the supervisor of the employee who made the decision. If the issue is not resolved at the supervisor's level, the interested person may request that the matter be reviewed at the next higher supervisory level. This process may continue through the agency's entire supervisory chain of command through the Centers to the Deputy Commissioner for Operations, and then to the Commissioner of Food and Drugs (the Commissioner).

FDA's formal processes are supplemented by several ombudsman offices to facilitate the resolution of disputes informally. The Office of the Chief Mediator and Ombudsman has been established within the Commissioner's Office to resolve intercenter disputes, disputes that have gone through the Center Directors but are still at issue, or other disputes where the complainant has concerns about raising the issue with a Center. Several FDA Centers have established Center Ombudsman's offices to resolve disputes most appropriately handled at the Center level. For further information about any FDA ombudsman office, contact the information contact persons listed previously.

In the **Federal Register** of June 16, 1998 (63 FR 32733 and 32772), FDA published a direct final rule and a companion proposed rule amending § 10.75 to add another method of resolving scientific controversies in light of section 404 of FDAMA. This amendment stated that sponsors, applicants, or manufacturers of drugs (including human drugs, animal drugs, and human biologics), or devices may request review of scientific controversies by an appropriate scientific advisory panel or advisory committee. (Hereafter in this document, the term advisory committee includes scientific advisory panels.) By this amendment, FDA clarified that sponsors, applicants, and manufacturers of drugs, biologics, and devices are not limited solely to requesting internal supervisory review, but also have the right to request review of scientific controversies by appropriate advisory committees. FDA believes that in appropriate circumstances, advisory committees can provide the agency with useful insight and advice about the resolution of scientific controversies.

FDA initially used the direct final rule approach to rulemaking because it believed the amendment to § 10.75 was noncontroversial and in accord with FDAMA. In accordance with FDA's procedures for direct final rulemaking, the direct final rule stated that if FDA received no significant adverse comments, the direct final rule would go into effect on October 29, 1998. The direct final rule stated further that if FDA received any significant adverse comments, it would withdraw the direct final rule and consider all comments received on the companion proposed rule in the development of a final rule

using the usual notice and comment rulemaking procedures. The comment period for the companion proposed rule ended on August 31, 1998. FDA received significant adverse comments in response to the direct final rule and the companion proposed rule. Therefore, in the **Federal Register** of September 23, 1998 (63 FR 50757), FDA withdrew the direct final rule.

The essence of the significant adverse comments was that the amendment to § 10.75 failed to provide a procedure that sponsors, applicants, and manufacturers could follow to request section 404 reviews. The comments suggested that the regulation called for by section 404 of FDAMA contain information such as the process for selecting members of an advisory committee convened to conduct a section 404 review, the timeframes for conducting the reviews, the standards for granting or denying a section 404 review, and the weight to be given to advisory committee recommendations.

FDA acknowledges the usefulness of much of this kind of information, but concludes that it should not be included in § 10.75. Because of the significant differences among FDA Centers in applicable laws, existing appeal and dispute resolution mechanisms, and approaches to advisory committee management, FDA is adopting a Center-based approach to the implementation of section 404 of FDAMA. Each affected Center is responsible for developing and administering its own processes for handling requests for section 404 reviews and is issuing a guidance document containing specific information of the type suggested by the comments. The substantive differences in the programs in the affected Centers, and the different matters that could be the subject of a request for advisory committee review, preclude inclusion of this type of information in § 10.75.

In this final rule, information that is applicable to all requests for section 404 review has been added to the language amending § 10.75. It is expected that Centers will fully evaluate each request for section 404 review, and will not unreasonably deny a sponsor, applicant, or manufacturer such review. The amendment to § 10.75 now provides that if a Center denies a request for section 404 review, the reason(s) for such denial will be set forth in writing to the requester. A Center's decision to deny section 404 review may be reviewed through the agency's supervisory chain of command, to the Deputy Commissioner for Operations, then to the Commissioner. Persons should ordinarily exhaust Center mechanisms for appealing denials of section 404 review before seeking review by the Deputy Commissioner. Denial of a request for section 404 review is not final agency action subject to judicial review.

Section 10.75 provides that requests for reviews of Center denials be submitted to the Chief Mediator and Ombudsman who shall, by informal means, facilitate the review of the denial on behalf of the Deputy Commissioner for Operations. The role of the Chief Mediator and Ombudsman in the review of a Center's denial of a request for section 404 review is to ensure that all appropriate means of informally resolving the dispute have been used before review by the Deputy Commissioner. The Chief Mediator and Ombudsman will not make an independent determination of whether a section 404 review should be granted, but will work informally with the Center and the person denied section 404 review, to develop a mutually acceptable approach, taking into account all relevant factors.

II. Response to Comments

FDA received five comments on the proposed rule; two from trade associations, one from a private company, one from a university medical clinic, and one from an FDA employee.

1. One comment objected to FDA's conclusion that it was required to issue a regulation establishing a procedure for requesting review of scientific controversies only if procedures to request review of scientific controversies do not otherwise exist. According to the comment, section 404 of FDAMA requires FDA to establish a procedure to be used when there are no other specific provisions for requesting review of the particular type of scientific controversy at issue.

FDA disagrees with this interpretation. Section 404 of FDAMA states ''If * * * there is a scientific controversy * * * and no specific provision of the Act * * * including a regulation * * * provides a right of review of the matter in controversy, the Secretary shall, by regulation, establish a procedure * * *.'' The plain language of section 404 of FDAMA is that FDA must establish a procedure if scientific controversies could arise for which the act or regulations currently provide no right of review. In light of § 10.75, which permits any interested person to obtain review of any FDA decision, FDA concludes that no additional procedure is required.

However, as explained in the proposed rule, notwithstanding the existence of this universal dispute resolution provision, FDA recognizes that in appropriate circumstances, review by an advisory committee can provide the agency with useful insight and advice about the resolution of a scientific controversy. For this reason, FDA is amending § 10.75 to indicate that sponsors, applicants, or manufacturers seeking review of scientific controversies are not limited to internal supervisory review, but may also request review by an advisory committee.

2. One comment asserted that Congress' intent in enacting section 404 of FDAMA was to provide a procedure for resolving disputes by expert committees who are not part of FDA's normal administrative processes. The comment also suggested that the procedure should solicit nominees from the public and FDA for inclusion on an advisory committee roster. According to the comment, the procedure should require prompt conflict of interest checks and periodic updates, in order to assure the timely disposition of controversies. In order to simplify the creation of a panel as much as possible, the comment suggested that the number of persons participating on each panel should be limited to three.

FDA disagrees with this comment. The comment did not identify any specific language in section 404 of FDAMA suggesting that a procedure must be developed to use committees outside FDA's normal advisory committee processes. In fact, section 404 of FDAMA suggests the opposite, by its references to sections 505(n) and 515(g)(2)(B) of the act (21 U.S.C. 355(n) and 360e(g)(2)(B)), the statutory provisions covering FDA's existing drug and device advisory committees.

As noted previously, FDA implementation of section 404 of FDAMA is Center-based. The Centers' existing advisory committee structures and processes for managing advisory committees provide significant flexibility. Each Center may tailor its current processes as necessary to ensure that section 404 reviews are conducted in a timely way by persons with appropriate qualifications.

3. Two comments suggested specific timeframes for conducting section 404 reviews, and a third comment requested additional information about the timeframe for section 404 review. One suggested timeframe would require that a committee be constituted within 10 days of a written request for review, and the request be immediately forwarded to the committee. Also within 10 days of the request, FDA would be required to state its agreement with or opposition to the substantive points in the request, and forward its response to the

committee. Within 20 days of the committee's receipt of FDA's response, a 21 CFR part 14 informal hearing would be convened, unless the parties agree to have the committee decide on the papers. If a hearing occurs, the committee would provide its written decision to the parties within 20 days after the end of the hearing. If there is no hearing, the committee's decision would be required no later than 20 days after the committee receives FDA's response to the request for review.

The second suggested timeframe would require FDA to respond to requests for section 404 review within 30 days. When review is granted, the issue would be presented to the committee within 60 days. FDA would be required to resolve the matter within 90 days of receiving the advisory committee's conclusions and recommendations.

FDA recognizes that section 404 of FDAMA requires that reviews take place in a timely manner, but concludes that specific timeframes should not be included in a regulation of general applicability. For example, the second suggested timeframe outlined previously appears to be based on the timeframes established in section 120 of FDAMA and performance goals associated with the reauthorization of the Prescription Drug User Fee Act (21 U.S.C. 379g *et seq.*), both of which apply only to human drugs and biologics. It would be inappropriate to develop general timeframes based on requirements and commitments that do not apply to all affected FDA Centers. Each Center's section 404 processes incorporate timeframes as appropriate, taking into account applicable statutory and regulatory provisions, existing appeal and dispute resolution mechanisms, and approaches to advisory committee management.

4. One comment suggested that representatives of the Office of the Chief Mediator and Ombudsman serve as executive secretaries of advisory committees convened to conduct section 404 reviews.

FDA disagrees with this suggestion. The efficiency of the Center-based approach to implementation of section 404 of FDAMA could be diminished by appointment of an executive secretary who is not an employee of the Center. Efficiency will be best promoted by using executive secretaries who are fully familiar with the advisory committee procedures. Center employees are most likely to have that expertise. The staff within the Office of the Chief Mediator and Ombudsman will continue to serve as an additional informal dispute resolution resource apart from the Centers.

5. A comment suggested that the advisory committee's conclusions should be accepted as binding unless FDA determines that the weight of record evidence does not support the decision, that the committee applied incorrect legal standards or that the committee otherwise acted inconsistently with the law.

FDA rejects this comment. Nothing in the language of section 404 of FDAMA, section 505(n) of the act, or section 515(g)(2)(B) of the act suggests that it would be appropriate to treat advisory committee recommendations as binding. Section 505(n) of the act contemplates convening advisory committees to provide ''expert scientific advice and recommendations * * *.'' When FDA receives a recommendation from an advisory committee convened under section 515(g)(2)(B) of the act, the agency is to affirm or reverse the order referred to the committee and state the reasons therefore. FDA accords the recommendations of all advisory committees significant weight, but believes it would be an unauthorized delegation of FDA authority to treat advisory committee recommendations as binding. FDA action on section 404 advisory committee recommendations is not final agency action subject to judicial review, unless otherwise required by law.

6. A comment suggested that FDA must grant advisory committee review unless the committee itself declines to review the issue. Another comment seemed to assume that all requests for section 404 reviews will be granted.

FDA disagrees with these comments. The plain language of section 404 of FDAMA provides sponsors, applicants, and manufacturers only the right to *request* review of a scientific controversy by an advisory committee. FDA believes that the agency, not a particular advisory committee, is in the best position to evaluate whether individual requests for section 404 review present appropriate issues to be raised before an advisory committee.

Furthermore, although FDA endorses section 404's goal of facilitating the resolution of disputes by expanding access to the independent experts who serve on advisory committees, it concludes that § 10.75 should include only those aspects of the process for obtaining section 404 reviews that are applicable to all affected Centers. Therefore, § 10.75 includes a general mandate that requests for section 404 reviews shall not be unreasonably denied, and provides information about the process to be followed if requests are denied.

To implement the rule's overall mandate that requests for section 404 reviews shall not be unreasonably denied, the Center guidance documents provide information about granting or denying requests. Although Centers differ with respect to applicable laws, existing appeal and dispute resolution mechanisms, and approaches to advisory committee management, there are some situations in which all Centers would be likely to conclude that a section 404 review would not be appropriate. For example, the nature of the dispute may not be amenable to advisory committee review, the controversy might be more quickly and easily resolved in some other manner, or the issue may not be material to FDA's ultimate decision. Additionally, a section 404 review would be appropriate only if the matter relates to agency action on the requesting sponsor's own product. For example, a section 404 review would not be appropriate if it were requested for anti-competitive purposes, such as to prolong the review of a competitor's product. Furthermore, some issues are reviewed by advisory committees under regulatory processes that already provide for advisory committee review, and so section 404 review may be inappropriate given the preceding, or subsequent, regulatory processes.

7. A comment suggested that the term ''scientific controversy'' be defined as ''one involving issues related to matters of technical expertise requiring some specialized education, training, or experience to understand and resolve.''

FDA concludes that a definition of scientific controversy is not necessary in § 10.75. The Center guidance documents may define a scientific controversy if the Centers conclude that a definition would be useful to its specific processes.

8. A comment suggested that § 10.75 outline the steps an applicant, sponsor, or manufacturer must take to request a section 404 review. Another comment also requested information about how the review will take place and the general content and required number of copies of requests.

FDA concludes that this information should not be included in § 10.75. Under the Center-based approach FDA has selected to implement section 404 of FDAMA, each Center is providing information about the steps an applicant, sponsor, or manufacturer must take to request a section 404 review in guidance documents. The Centers' processes are tailored to take into account their applicable statutory

and regulatory provisions, existing appeal and dispute resolution mechanisms, and approaches to advisory committee management. It would not be feasible to incorporate all these particulars in one regulation of general applicability.

9. One of the comments interpreted the proposed amendment to § 10.75 to require applicants, sponsors, and manufacturers to seek review through the supervisory chain before submitting a request for a section 404 review.

FDA concludes that this issue is most appropriately addressed in Center-guidance documents rather than § 10.75. The points at which it is appropriate to request a section 404 review will vary depending on the scientific issue presented, the regulatory mechanism involved, and the relevant Center's organizational structure. Both the applicant, sponsor, or manufacturer and the agency have an interest in resolving scientific controversies at the earliest appropriate time.

10. Two comments suggested that persons other than sponsors, manufacturers, and applicants be given the right to request a review of a scientific controversy under section 404 of FDAMA. According to one comment, physicians, pharmacists, and/or their professional organizations should be permitted to request section 404 reviews. The comment identified compounding and unlabeled indications as potential sources of scientific controversy that might benefit from review under section 404 of FDAMA. The other comment requested that FDA employees be permitted to request review of disputes by advisory committees. According to this comment, advisory committee reviews would enable FDA to resolve issues with greater public input and on a more timely basis.

FDA disagrees with the suggestions that persons other than sponsors, manufacturers, and applicants be given the right to request a review of a scientific controversy under section 404 of FDAMA. By limiting the right to request a section 404 review to sponsors, applicants, and manufacturers, Congress indicated the kind of scientific controversies it had in mind: Those arising within the context of FDA's regulation of a specific product. Thus, a section 404 review would not be available to resolve broad public health controversies unrelated to the regulation of a specific product, or to resolve FDA's policy issues. The agency will continue to use 21 CFR part 15 hearings, public meetings, and advisory committee meetings to help resolve general scientific and policy issues.

Moreover, FDA regulations provide persons other than sponsors, applicants, and manufacturers other processes for seeking review of FDA decisions. Citizen petitions may be submitted by any person. A citizen petition may request the Commissioner to issue, amend, or revoke any regulation or order, or to take or refrain from taking any other form of administrative action. (See 21 CFR 10.30.) Any person may request reconsideration of part or all of a decision made by the Commissioner in response to any type of administrative petition. (See 21 CFR 10.33 and 10.25.) Finally, as noted in the proposed rule, any person may request review of any decision made by an FDA employee, other than the Commissioner, on any matter. (See § 10.75.)

11. Two comments expressed concern that FDA could retaliate against persons who request section 404 reviews, and for this reason suggested that persons be permitted to request section 404 reviews on behalf of sponsors, manufacturers and applicants, or that persons be permitted to request section 404 reviews anonymously.

Although FDA takes concerns about retaliation very seriously, it disagrees with the comment because, as explained in the previous response, the comments' proposed changes have the potential to significantly change the kinds of controversies reviewed under section 404.

FDA reiterates and reaffirms its commitment to an environment in which challenges to agency decisions can be raised without fear of adverse consequences. By memo dated June 29, 1995, Commissioner Kessler reminded all FDA employees that companies are free to vigorously challenge agency positions and requirements, and to freely voice their views. By letter of the same date, Commissioner Kessler assured members of Congress that any act or threat of retaliation by any FDA employee is totally unacceptable and will not be tolerated. Anyone who believes retaliation has occurred, or is likely to occur, is urged to contact the Center Ombudsmen, Center Management, or the Office of the Chief Mediator and Ombudsman. If merited, specific allegations of retaliation will be forwarded to FDA's Office of Internal Affairs which investigates allegations of employee misconduct in cooperation with the Department's Inspector General's Office. FDA believes that its employees are highly sensitive to the need to avoid even the appearance of impropriety, and strive to make complex clinical, scientific, legal, and factual decisions fairly and even-handedly. Accordingly, FDA believes that sponsors, manufacturers, and applicants will not be dissuaded from requesting review of issues under section 404 of FDAMA.

III. Agency Guidance

As explained previously, each FDA Center is providing detailed information in guidance documents about the implementation of section 404 of FDAMA. For further information, see the **FOR FURTHER INFORMATION CONTACT** section of this document.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121)) and the Unfunded Mandate Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule does not impose any requirements on the regulated industry, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VI. Paperwork Reduction Act of 1995

The final rule contains no new collections of information. Therefore,

clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 10

Administrative practice and procedure, News media.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and authority delegated to the Commissioner of Food and Drugs, 21 CFR part 10 is amended as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

1. The authority citation for 21 CFR part 10 continues to read as follows:

Authority: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

2. Section 10.75 is amended by redesignating paragraph (b) as paragraph (b)(1) and by adding paragraph (b)(2) to read as follows:

§ 10.75 Internal agency review of decisions.

* * * * *

(b)(1) * * *

(2) A sponsor, applicant, or manufacturer of a drug or device regulated under the act or the Public Health Service Act (42 U.S.C. 262), may request review of a scientific controversy by an appropriate scientific advisory panel as described in section 505(n) of the act, or an advisory committee as described in section 515(g)(2)(B) of the act. The reason(s) for any denial of a request for such review shall be briefly set forth in writing to the requester. Persons who receive a Center denial of their request under this section may submit a request for review of the denial. The request should be sent to the Chief Mediator and Ombudsman.

Dated: November 12, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–30812 Filed 11–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 97N–0524]

RIN 0910–AA43

Food Labeling: Warning and Notice Statement: Labeling of Juice Products; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration is correcting a final rule that appeared in the **Federal Register** of July 8, 1998 (63 FR 37030). The final rule revised the food labeling regulations to require a warning statement on fruit and vegetable juice products that have not been processed to prevent, reduce, or eliminate pathogenic microorganisms that may be present. The document was published with several inadvertent editorial errors. This document corrects those errors.

DATES: The regulation is effective September 8, 1998; however, compliance for juice other than apple juice and apple cider is not required until November 5, 1998.

FOR FURTHER INFORMATION CONTACT: Geraldine A. June, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

In FR Doc. No. 98–18287, appearing in the **Federal Register** of Wednesday, July 8, 1998, the following corrections are made:

1. On page 37038, in the third column, in the fourth full paragraph, in the sixth line, ''(Ref. 9)'' is corrected to read ''(Ref. 7)''.

2. On page 37040, in the first column, in the last line of the first full paragraph, ''(Ref. 10)'' is corrected to read ''(Ref. 8)''.

3. On page 37040, in the third column, in the second full paragraph, in the eleventh line, ''(Ref. 11)'' is corrected to read ''(Ref. 9)'' and in that same paragraph, in the fifteenth and eighteenth lines, ''(Ref. 12)'' is corrected to read ''(Ref. 10)''.

5. On page 37041, in the last line of the third column, ''(Ref. 13)'' is corrected to read ''(Ref. 11)''.

6. On page 37044, in the third column, in the fourth paragraph, in the twenty-fifth line, ''(Ref. 14)'' is corrected to read ''(Ref. 12)''.

7. On page 37047, in the second column, in the second full paragraph, in the twentieth line, ''(Ref. 15)'' is corrected to read ''(Ref. 13)''.

§ 101.17 [Corrected]

8. On page 37056, in the third column, in § 101.17(g)(7)(i)(B), beginning in the fourth line, ''Hazard Analysis Critical Control Points'' is corrected to read ''Hazard Analysis and Critical Control Point''.

Dated: November 10, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–30814 Filed 11–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Fenbendazole Suspension; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulation concerning veterinary prescription use of Hoechst Roussel Vet's fenbendazole suspension for cattle. The amendment clarifies the oral dose of fenbendazole suspension used as a dewormer in cattle.

EFFECTIVE DATE: November 18, 1998.

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7575.

SUPPLEMENTARY INFORMATION: Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059, is sponsor of new animal drug application (NADA) 128–620 that provides for oral, veterinary prescription use of Panacur® (fenbendazole) 10 percent suspension. The drug is used as a dewormer in cattle, including dairy cattle of breeding age at 5 milligrams per kilogram (mg/kg) of body weight, and only in beef cattle at 10 mg/kg of body weight. The regulations are amended in 21 CFR 520.905a to clarify the approval.

The amendments clarify the drug dose used to treat various classes of animals and insert certain technical revisions. No additional safety or effectiveness data were required. A revised freedom