Additives: Polymers (21 CFR 177) to provide for the safe use of polyphenylene sulfone resins as articles or components of articles intended for repeated use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the 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.

Dated: February 26, 1999.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–6750 Filed 3–18–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0297]

Draft Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Formal Dispute Resolution: Appeals Above the Division Level.'' This draft guidance is intended to provide guidance for industry on procedures that will be adopted by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) for resolving scientific and procedural disputes that cannot be resolved at the division level.

DATES: Written comments on the draft guidance document may be submitted by May 18, 1999. General comments on agency guidance documents are welcome at any time. Submit written comments on the information collection provisions by April 19, 1999.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or ''http://www.fda.gov/cber/guidelines.htm''. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, or FAX 888–CBERFAX or 301–827–3844. Send two self-addressed adhesive labels to assist the office in processing your request. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Patricia L. DeSantis, Center for Drug Evaluation and Research (HFD–2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400, or

Rebecca A. Devine, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Description of the Guidance

FDA is announcing the availability of a draft guidance for industry entitled ''Formal Dispute Resolution: Appeals Above the Division Level.'' The draft guidance is intended to provide guidance for industry on procedures that will be adopted by CDER and CBER for resolving scientific and procedural disputes that cannot be resolved at the division level. This draft guidance describes procedures for formally appealing such disputes to the office or center level and for submitting information to assist agency officials in resolving the issue(s) presented.

FDA regulations § 10.75 (21 CFR 10.75) provide a mechanism for any interested person to obtain formal 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 primary supervisory 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. CDER and CBER regulations for dispute resolution during the investigational new drug (IND) process (§ 312.48 (21 CFR 312.48)) and the new drug application (NDA)/abbreviated new drug application (ANDA) process (§ 314.103 (21 CFR 314.103)) establish similar procedures for the resolution of scientific and procedural matters at the division level and subsequent formal review of decisions through center management.

On November 21, 1997, President Clinton signed into law the Food and Drug Administration Modernization Act of 1997 (the Modernization Act) (Pub. L. 105–115). Section 404 of the Modernization Act creates new section 562 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360bbb–1). Section 562 of the act provides that if, regarding an obligation concerning drugs or devices under the act or section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262), there is a scientific dispute between the agency and a sponsor, applicant, or manufacturer, and no specific provision of the act or regulation provides a right of review of the matter in controversy, FDA shall, by regulation, establish a procedure under which such sponsor, applicant, or manufacturer may request a review of the controversy, including review by an advisory committee. Section 562 of the act further provides that such review of the controversy shall take place in a timely manner. In the **Federal Register** of November 18, 1998 (63 FR 63978), FDA amended § 10.75 to explicitly state that a sponsor, applicant, or manufacturer of a drug or device may request review of a scientific controversy by an appropriate advisory committee. In the preamble to the final rule, FDA stated that implementation of this provision would be undertaken by the individual FDA centers and would be described in guidance documents.

The Prescription Drug User Fee Act of 1992 (PDUFA) (Pub. L. 102–571) was reauthorized in November 1997 (PDUFA 2) as part of the Modernization Act. In conjunction with PDUFA 2, FDA agreed to specific performance goals (PDUFA goals) for activities associated with the development and review of products in human drug applications as defined in section 735(1) of the act (21 U.S.C. 379g(1)) (PDUFA products). The PDUFA goals are summarized in ''PDUFA Reauthorization Performance Goals and Procedures,'' an enclosure to a letter dated November 12, 1997, from the Secretary of Health and Human Services, Donna E. Shalala, to Senator James M. Jeffords. The PDUFA goals for major dispute resolution describe specific timeframes for CDER and CBER response to formally appealed decisions regarding scientific or procedural matters concerning PDUFA products.

The policies and procedures described in this draft guidance document will implement agency

regulations, section 562 of the act, and the PDUFA goals for dispute resolution. Unless stated otherwise in the draft guidance, the document applies to PDUFA products and non-PDUFA products (e.g., generic drugs).

This draft Level 1 guidance is being issued consistent with FDA's ''Good Guidance Practices'' (62 FR 8961, February 27, 1997). It represents the agency's current thinking on formal dispute resolution in CDER and CBER. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes, regulations, or both.

II. Comments

Interested persons may, on or before May 18, 1999, submit to the Dockets Management Branch (address above) written comments on the draft guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth below.

With respect to the following collection of information, FDA invites comment on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Draft Guidance for Industry on Formal Dispute Resolution: Appeals Above the Division Level.

Description: FDA is issuing a draft guidance on the process for formally resolving scientific and procedural disputes in CDER and CBER that cannot be resolved at the division level. The draft guidance describes procedures for formally appealing such disputes to the office or center level and for submitting information to assist center officials in resolving the issue(s) presented. The draft guidance provides information on how the agency will interpret and apply provisions of the existing regulations regarding internal agency review of decisions (§ 10.75) and dispute resolution during the IND process (§ 312.48) and the NDA/ANDA process (§ 314.103). In addition, the draft guidance provides information on how the agency will interpret and apply the specific PDUFA goals for major dispute resolution associated with the development and review of PDUFA products.

Existing regulations, which appear primarily in parts 10, 312, and 314 (21 CFR parts 10, 312, and 314), establish procedures for the resolution of scientific and procedural disputes between interested persons and the agency, CDER, and CBER. All agency decisions on such matters are based on information in the administrative file (§ 10.75(d)). In general, the information in an administrative file is collected under existing regulations in parts 312 (OMB Control No. 0910–0001), 314 (OMB Control No. 0910–0014), and part 601 (21 CFR part 601) (OMB Control No. 0910–0315), which specify the information that manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of drugs and biological products. This information is usually submitted as part of an IND, NDA, or biologics license application (BLA), or as a supplement to an approved application. While FDA already possesses in the administrative file the information that would form the basis of a decision on a matter in dispute resolution, the submission of particular information regarding the request itself and the data and information relied on by the requestor in the appeal would facilitate timely resolution of the dispute. The draft guidance describes the following collection of information not expressly specified under existing regulations: The submission of the request for dispute resolution as an amendment to the application for the underlying product, including the submission of supporting information with the request for dispute resolution.

Agency regulations (§§ 312.23(11)(d), 314.50, 314.94, and 601.2) state that information provided to the agency as part of an IND, NDA, ANDA, or BLA is to be submitted in triplicate and with an appropriate cover form. Form FDA 1571 must accompany submissions under IND's and Form FDA 356h must accompany submissions under NDA's, ANDA's, and BLA's. Both forms have valid OMB control numbers as follows: FDA Form 1571, OMB Control No. 0910–0014, expires December 31, 1999; and FDA Form 356h, OMB Control No. 0910–0338, expires April 30, 2000.

In the draft guidance document, CDER and CBER ask that a request for formal dispute resolution be submitted as an amendment to the application for the underlying product and that it be submitted to the agency in triplicate with the appropriate form attached, either Form FDA 1571 or Form FDA 356h. The agency recommends that a request be submitted as an amendment in this manner for two reasons: To ensure that each request is kept in the administrative file with the entire underlying application and to ensure that pertinent information about the request is entered into the appropriate tracking databases. Use of the information in the agency's tracking databases enables the appropriate agency official to monitor progress on the resolution of the dispute and to ensure that appropriate steps will be taken in a timely manner.

CDER and CBER have determined and the draft guidance recommends that the following information should be submitted to the appropriate center with each request for dispute resolution so that the Center may quickly and efficiently respond to the request:

- A brief but comprehensive statement of each issue to be resolved, including a description of the issue, the nature of the issue (i.e., scientific, procedural, or both), possible solutions based on information in the administrative file, whether informal dispute resolution was sought prior to the formal appeal, whether advisory committee review is sought, and the expected outcome;
- A statement identifying the review division/office that issued the original decision on the matter and, if applicable, the last agency official that attempted to formally resolve the matter;
- A list of documents in the administrative file, or additional copies of such documents, that are deemed

necessary for resolution of the issue(s); and

• A statement that the previous supervisory level has already had the opportunity to review all of the material relied on for dispute resolution. The information that the agency suggests submitting with a formal request for dispute resolution consists of: (1) Statements describing the issue from the perspective of the person with a dispute, (2) brief statements describing the history of the matter, and (3) documents previously submitted to FDA under an OMB approved collection of information (see previous discussion).

Based on FDA's experience with dispute resolution, the agency expects that most persons seeking formal dispute resolution will have gathered the materials listed previously when identifying the existence of a dispute with the agency. Consequently, FDA anticipates that the collection of information attributed solely to the guidance will be minimal.

Description of Respondents: A sponsor, applicant, or manufacturer of a drug or biologic product regulated by the agency under the act or section 351 of the PHS Act who requests formal resolution of a scientific or procedural dispute.

Burden Estimate: Table 1 of this document provides an estimate of the annual reporting burden for requests for dispute resolution. In fiscal year (FY) 1998, 39 sponsors and applicants (respondents) submitted requests for formal dispute resolution to CDER and 12 respondents submitted requests for formal dispute resolution to CBER. Although the procedures for requesting formal dispute resolution that are set forth in the draft guidance document were not in place in FY 1998, FDA estimates that the number of respondents who would submit requests for dispute resolution under the guidance would remain the same. The total annual responses are the total number of requests submitted to CDER and CBER in 1 year, including requests for dispute resolution that a single respondent submits more than one time. In FY 1998, CDER received approximately 49 requests and CBER received approximately 15 requests. The agency estimates that the total annual responses will remain the same, averaging to 1.26 responses per respondent. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a request for formal dispute resolution in accordance with this draft guidance, including the time it takes to gather and copy brief statements describing the issue from the perspective of the person with the dispute, brief statements describing the history of the matter, and supporting information that has already been submitted to the agency. Based on experience, FDA estimates that approximately 8 hours on average would be needed per response. Therefore, FDA estimates that 512 hours will be spent per year by respondents requesting formal dispute resolution under the guidance.

FDA invites comments on this analysis of information collection burdens.

TABLE 1.—Estimated Annual Reporting Burden[1]

Requests for Formal Dispute Resolution	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
CDER	39	1.26	49	8	392
CBER	12	1.25	15	8	120
Total					512

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

In compliance with section 3507(d) of the PRA (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this draft guidance to OMB for review. Interested persons are requested to send comments on this information collection by April 19, 1999, to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

Dated: March 15, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–6749 Filed 3–18–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0302]

Draft ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #2;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #2.'' This draft guidance is neither final nor is it in effect at this time. The final regulations implementing the Mammography Quality Standards Act of 1992 (the MQSA) will become effective April 28, 1999, and will replace the interim regulations which, under the MQSA, currently regulate mammography facilities. The draft guidance document is intended to assist facilities and their personnel to meet the MQSA final regulations.

DATES: Written comments concerning this draft guidance must be received by June 17, 1999.

ADDRESS: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #2'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Written comments concerning this draft guidance must be submitted to the Dockets Management Branch (HFA–