with the regulatory philosophy and principles identified in the Executive Order. In addition, the reclassification actions are not significant regulatory actions as defined by the Executive Order and so are 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. Reclassification of the devices from class III to class II will relieve manufacturers of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that these reclassification actions, if finalized, will not have a significant economic impact on a substantial number of small entities. In addition, this reclassification action will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis pursuant to section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

XIII. Request for Comments

Interested persons may, on or before June 7, 2000, submit to the Dockets Management Branch (address above) written comments regarding this document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m. Monday through Friday.

Dated: February 14, 2000.

Linda S. Kahan,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 00–5467 Filed 3–6–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0297]

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 guidance for industry entitled ''Formal Dispute Resolution: Appeals Above the Division Level.'' This 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: Submit written comments on agency guidances at any time.

ADDRESSES: Copies of this 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 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 the 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, FAX 888–CBERFAX. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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

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

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance entitled ''Formal Dispute Resolution: Appeals Above the Division Level.'' The 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. The 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.

In the **Federal Register** of March 19, 1999 (64 FR 13587), FDA announced the availability of a draft guidance for industry entitled ''Formal Dispute Resolution: Appeals Above the Division Level.'' The agency has finalized this guidance after considering comments received on the draft version. Few comments were received, and minor changes were made to the draft version in response to the comments in an effort to make the document more clear.

FDA regulations 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 Commissioner of Food and Drugs. CDER and CBER regulations for dispute resolution during the investigational new drug process (21 CFR 312.48) and the new drug application/abbreviated new drug application process (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) (Public Law 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 (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 21 CFR 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 (Public Law 102–571) (PDUFA) 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 guidance document will implement agency regulations, section 562 of the act, and the PDUFA goals for dispute resolution. Unless stated otherwise in the guidance, the document applies to PDUFA products and non-PDUFA products (e.g., generic drugs).

In the notice announcing the availability of the draft version of this guidance, FDA published notice of the proposed collection of information related to the guidance. The **Federal Register** notice also requested comments on the burden estimates for the guidance document. In the **Federal Register** of August 15, 1999 (64 FR 46397), the agency announced that it was submitting the collection of information to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. The information collection provisions related to this guidance document have been approved under OMB control number 0910–0430. This approval expires December 31, 2002. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

This Level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The guidance 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.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). 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 guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 29, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–5465 Filed 3–6–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0296]

Guidance for Industry on Formal Meetings With Sponsors and Applicants for PDUFA Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Formal Meetings with Sponsors and Applicants for PDUFA Products.'' This guidance is intended to provide guidance to 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 formal meetings between the agency and sponsors or applicants concerning certain drug products.

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Copies of the 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 this 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 to the 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, FAX 888–CBERFAX. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), 1401 Rockville Pike, Rockville, MD 20852–448, 301–827–0373.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Formal Meetings with Sponsors and Applicants for PDUFA Products.''This guidance is intended to provide guidance to industry on procedures that will be adopted by CDER and CBER for formal meetings between the agency and sponsors or applicants concerning certain drug products.

In the **Federal Register** of March 19, 1999 (64 FR 13591), FDA announced the availability of a draft version of this guidance. The agency has finalized that draft guidance after considering comments received on the draft version. Few comments were received, and only minor changes were made to the draft version in response to the comments in an effort to make the document clearer.

CDER and CBER participate in many meetings each year with sponsors of investigations and applicants for marketing who seek guidance relating to the development and review (including the initial launch) of products in human drug applications as defined in section 735(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379g(1)) (PDUFA products). These meetings often represent critical points in the regulatory process. It is essential that FDA maintain procedures for the