day before the meeting at: *www.fda.gov/ohrms/dockets/ac/acmenu.htm.*

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 25, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on March 4, 2003, and between approximately 8:30 a.m. and 9 a.m. and 11:30 a.m. and 12 noon on March 5, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 25, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact LaNise Giles at 301–827–7001 at least 7 days in advance of the meeting.

FDA regrets that it was unable to publish this notice 15 days prior to the March 4, 2003, Arthritis Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Arthritis Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 13, 2003.

Linda Arey Skladany,

Associate Commissioner for External Affairs.

[FR Doc. 03–4350 Filed 2–24–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0061]

Draft Guidance for Industry on Comparability Protocols—Chemistry, Manufacturing, and Controls Information; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Comparability Protocols—Chemistry, Manufacturing, and Controls Information.'' This draft document provides recommendations to applicants on preparing and using comparability protocols for postapproval changes in chemistry, manufacturing, and controls (CMC) information.

DATES: Submit written or electronic comments on the draft guidance by June 25, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Training and Communications, Division of Communications Management, Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857; or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448 or to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit phone requests to 800–835–4709 or 301–827–1800. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Stephen Moore, Center for Drug Evaluation and Research (HFD–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6430, or Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–1), Food and Drug Administration, 8800 Rockville Pike, Rockville, MD 20892, 301–435–5681, or Dennis Bensley, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6956.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Comparability Protocols—Chemistry, Manufacturing, and Controls Information.'' This draft guidance applies to comparability protocols that would be submitted in new drug applications (NDAs), abbreviated new drug applications (ANDAs), new animal drug applications (NADAs), abbreviated new animal drug applications (ANADAs), or supplements to these applications, except for applications for protein products. Well-characterized synthetic peptides submitted in these applications are included within the scope of this guidance. This draft guidance also applies to comparability protocols submitted in drug master files (DMFs) and veterinary master files (VMFs) that are referenced in these applications. A separate guidance will address comparability protocols for proteins as well as for peptide products outside the scope of this guidance that are submitted in these applications. This separate guidance will also address comparability protocols for products submitted in biologics license applications (BLAs).

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control numbers 0910–0001 and 0910–0032.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on ''Comparability Protocols; Chemistry, Manufacturing, and Controls Information''. 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 and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (see

ADDRESSES) written or electronic comments on the draft guidance. Submit a single copy of electronic comments to http://www.fda.gov/dockets/ecomments or two hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft 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.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at http://www.fda.gov/cder/guidance/index.htm, http://www.fda.gov/cber/guidelines.htm, or http://www.fda.gov/cvm/guidance/published.htm.

Dated: February 19, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–4311 Filed 2–20–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drugs Administration

Medical Device User Fee Payment Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the payment procedures for medical device user fees for fiscal year (FY) 2003. The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), authorizes FDA to collect user fees for certain medical device applications. The FY 2003 fee rates were published in the **Federal Register** of November 21, 2002 (67 FR 70228 at 70229, as amended by the **Federal Registers** of January 10, 2003, and January 22, 2003 (68 FR 1469 and 68 FR 3033)); however, FDA could not begin to collect these fees until enabling appropriations were enacted. Those enabling appropriations were enacted on February 20, 2003, so FDA is now able to collect Medical Device User Fees for FY 2003. Accordingly, FDA will issue invoices for all fees payable for applications submitted between October 1, 2002, and March 31, 2003. Those invoices will be due and payable within 30 days of issuance. For all applications submitted on or after April 1, 2003, fees must be paid at the time that applications are submitted to FDA. This notice provides payment procedures for those submitting medical device applications that may be subject to user fees.

FOR FURTHER INFORMATION CONTACT: For further information on MDUFMA visit the FDA Web site *http://www.fda.gov/oc/mdufma* or contact James G. Norman, Office of Systems and Management (HFZ–2), Food and Drug Administration, Center for Devices and Radiological Health (CDRH), 9200 Corporate Blvd., Rockville, MD 20850, 301–827–6829.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 737 and 738 of the act (21 U.S.C. 379i and j) establish fees for certain medical device applications and supplements. When certain conditions are met, FDA may waive or reduce fees (21 U.S.C. 379j(d) and (e)).

MDUFMA establishes aggregate revenue amounts for application fee revenues each year for FY 2003 through FY 2007. Revenue amounts established for years after FY 2003 are subject to adjustment for inflation, workload, and revenue shortfalls from previous years. FDA will set and publish fees each year so that total revenues will approximate the levels established in the statute, after those amounts have been adjusted for inflation, workload, and, if required, revenue shortfalls from previous years.

II. What Are the Fees for Applications Submitted in FY 2003?

Table 1 of this document provides fee rates for applications submitted on October 1, 2002, and remaining in effect through September 30, 2003, as previously published (67 FR 70228 at 70229, as amended by 68 FR 1469 and 68 FR 3033).

TABLE 1—FEE TYPES, PERCENT OF PMA FEE, AND FY 2003 FEE RATES

Application Fee Type	Full Fee Amount as a Percent of PMA Fee	FY 2003 Full Fee	FY 2003 Small Business Fee
Premarket Approval (PMA), Product Development Protocol (PDP), Biologic License Application (BLA) (submitted under section 515(c) or (f) of the act (21 U.S.C. 360e(c) or (f)) or section 351 of the Public Health Service Act (the PHS Act) , respectively)	100	$154,000	$58,520
Premarket Report (PMR)(submitted under section 515(c)(2) of the act)	100	$154,000	$58,520
Panel Track Supplement (submitted under section 515 of the act to an approved PMA, PDP, or PMR that requests a significant change in design or performance of the device, or a new indication for use of the device, and for which clinical data are generally necessary to provide reasonable assurance of safety and effectiveness)	100	$154,000	$58,520
Efficacy Supplement (submitted under section 351 of the PHS Act to an approved BLA)	100	$154,000	$58,520
180-Day Supplement (submitted under section 515 of the act to an approved PMA, PDP or PMR that is not a panel track supplement and requests a significant change in components, materials, design, specification, software, color additives, or labeling)	21.5	$33,110	$12,582