Bioresearch Monitoring (BIMO) Inspection Programs)— This panel will discuss the agency's progress in developing various qualitative performance goals, such as those related to the modular PMA and GMP inspection programs. This panel will also discuss internally-established milestones for the BIMO inspection process.

• Third-Party Inspection Program— This panel will discuss implementing guidances for the program, including establishment eligibility criteria for inspection by a third party.

• Reuse— This panel will discuss the FDA-identified reprocessed single-use devices that require submission of certain validation data and the guidance that describes the agency's review procedures for such submissions. This panel will also report on FDA's progress in reviewing the validation data submissions.

At the conclusion of the meeting, there will be a general discussion from the floor.

III. Registration

Online registration for the meeting is required by October 22, 2004. Acceptance will be on a first-come, first-served basis. There will be no onsite registration. Please register online at *http://www.fda.gov/cdrh/meetings/120303.html*. FDA is pleased to provide the opportunity for interested persons to listen from a remote location to the live proceedings of the meeting. In order to ensure that a sufficient number of call-in lines are available, please register to listen to the meeting at *http://www.fda.gov/cdrh/meetings/120303.html* by October 22, 2004. Persons without Internet access may register for the onsite meeting or to listen remotely by calling 301–443–6597, ext. 121 by October 22, 2004.

If you need special accommodations due to a disability, please contact Cindy Garris at 301–443–6597, ext. 121 at least 7 days in advance.

IV. Request for Suggestions, Recommendations, and Materials

FDA is particularly interested in receiving suggestions from stakeholders on other topics for discussion. The agency is interested in receiving recommendations about other provisions yet to be implemented both in terms of their priority for implementation and specifics on the implementation itself. Send suggestions or recommendations to the Division of Dockets Management (see **ADDRESSES**).

FDA will place an additional copy of any material it receives on the docket for this document (2004N–0423). Suggestions, recommendations, and materials may be seen at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday (see **ADDRESSES**).

V. Transcripts

Following the meeting, transcripts will be available for review at the Division of Dockets Management (see **ADDRESSES**).

Dated: September 22, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–21676 Filed 9–27–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0422]

Guidance for Industry: Animal Drug Sponsor Fees Under the Animal Drug User Fee Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance (#173) entitled ''Guidance For Industry: Animal Drug Sponsor Fees Under the Animal Drug User Fee Act (ADUFA).'' This draft guidance describes how FDA intends to implement the Federal Food, Drug, and Cosmetic Act (the act) as it relates to animal drug sponsor fees.

DATES: Submit written or electronic comments on the draft guidance by October 28, 2004, to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance document to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the draft guidance document to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Comments should be identified with the full title of the draft guidance document and the docket number found in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: David Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6967, e-mail: *dnewkirk@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The Animal Drug User Fee Act of 2003 (ADUFA), enacted on November 18, 2003, amends the act by adding sections 739 and 740 (21 U.S.C. 379j-11 and 379j-12). Section 740 requires FDA to assess and collect user fees for certain applications, products, establishments, and sponsors. This draft guidance represents FDA's current thinking on how it intends to implement the animal drug sponsor fee provision of ADUFA.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Significance of Guidance

This draft guidance is being issued as a level 1 guidance consistent with our good guidance practices regulation (21 CFR 10.115). It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate method may be used as long as it satisfies the requirements of the applicable statutes and regulations.

III. Comments

This draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this draft guidance document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Electronic comments may be submitted on the Internet at *http://www.fda.gov/dockets/ecomments*. Once on this site, select [2004D–0422]

''Guidance for Industry: Animal Drug Sponsor Fees Under the Animal Drug User Fee Act'' and follow the directions. Copies of this guidance may be obtained on the Internet from the CVM home page at *http://www.fda.gov/cvm*.

Dated: September 21, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–21677 Filed 9–27–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0410]

Draft Guidance for Industry and Food and Drug Administration Staff: Application User Fees for Combination Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry and FDA Staff: Application User Fees for Combination Products.'' This draft guidance provides guidance to industry and FDA staff on marketing application user fees for combination products. The guidance also describes how the ''barrier to innovation'' waiver provision under the prescription drug user fee provisions of the Federal Food, Drug, and Cosmetic Act (act) may be applied to innovative combination products in the infrequent situation where FDA requires the submission of two marketing applications.

DATES: Submit written or electronic comments on this draft guidance by November 29, 2004 to ensure their adequate consideration in preparation of the final guidance. 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 Combination Products, 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Mark D. Kramer, Office of Combination Products (HFG–3), Food and Drug Administration, 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855, 301–427–1934.

SUPPLEMENTARY INFORMATION:

I. Background

A combination product is a product comprised of any combination of a drug and a device; a biological product and a device; a drug and a biological product; or a drug, device and a biological product. Depending upon the type of combination product, approval, clearance or licensure may be obtained through submission of a single marketing application, or through separate marketing applications for the individual constituent parts of the combination product. For most combination products, a single marketing application is sufficient for the product's approval, clearance, or licensure. In some cases, two marketing applications may be submitted for a combination product when one application would suffice. For example, a sponsor may choose to submit two applications when one would suffice in order to receive some benefit from having two applications. In other cases, FDA may determine that two marketing applications are necessary.

In 1992, Congress passed the Prescription Drug User Fee Act (PDUFA). PDUFA authorized FDA to collect fees from companies that produce certain human drug and biological products. The Medical Device User Fee and Modernization Act of 2002 amended the act to provide for user fees for the review of device applications. When a company requests approval of a new drug, device or biological product prior to marketing, it must submit an application along with a fee to support the review process.

This document provides guidance to industry and FDA staff on marketing application user fees for combination products as defined under 21 CFR 3.2(e). The guidance document explains that combination products for which a single marketing application is submitted will be assessed the user fee associated with that particular type of marketing application. The document explains that, if a sponsor chooses to submit two marketing applications when one would suffice, a user fee for each application would ordinarily be assessed. The document also explains that, in the infrequent situation where FDA requires two marketing applications for a combination product, two application fees would ordinarily be assessed. However, the guidance also describes how the PDUFA ''barrier to innovation'' waiver provision may be applied to innovative combination products for which FDA requires the submission of two marketing applications. Such a waiver would provide a reduction in application user fees equivalent to the additional fee burden associated with the submission of two marketing applications. This guidance does not address how FDA will determine whether a single marketing application or multiple marketing applications should be submitted for a combination product. Such guidance is in development and will be provided separately for public review and comment.

II. Significance of Guidance

This draft guidance document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized will represent the agency's current thinking on application user fees for combination products. 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 statute and regulations.

III. Electronic Access

To receive ''Guidance for Industry and FDA Staff: Application User Fees for Combination Products,'' you may either send a fax request to 301–427–1935, or an e-mail request to *combination@fda.gov* to receive a hard copy or electronic copy of the document.

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/oc.combination/default.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

IV. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the