Contamination in Drugs and Biological Products.'' During January through June 1999, some poultry, swine, and ruminants in several European Union (EU) countries were fed with animal feed of Belgian origin contaminated with dioxins and polychlorinated biphenyls (PCB's). Manufacturers who are using materials derived from such animal sources in the manufacture of their products should verify that the materials they are using are not derived from animals affected during the contamination incident, or conduct suitable testing of the materials.

DATES: Written comments on this guidance may be submitted at any time. General comments on agency guidances are welcome at any time.

ADDRESSES: Submit written comments to:

1. Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for copies of this guidance to:

2. Office of Training and Communications, Division of Communications Management, Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, http://www.fda.gov/cder/guidance/index.htm; or

3. 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; http://www.fda.gov/cber/guidelines.htm; FAX: 1–888–CBERFAX or 301–827–3844, or call the Voice Information System at 800–835–4709 or 301–827–1800; or

4. Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), 7500 Standish Pl., Rockville, MD 20855; 301–594–1755, http://www.fda.gov/cvm.

FOR FURTHER INFORMATION CONTACT:

Eric P. Duffy, Center for Drug Evaluation and Research (HFD–325), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–0098;

Christopher C. Joneckis, Center for Biologics Evaluation and Research (HFM–20), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–5318; or

John C. Matheson, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855, 301–827–6649.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Possible Dioxin/PCB Contamination in Drugs and Biological Products.'' During January through June 1999, some poultry, swine, and ruminants in several EU countries were fed with animal feed of Belgian origin contaminated with dioxins and PCB's. As a result, animals that received the contaminated feed have become contaminated with dioxins and PCB's. Manufacturers who are using materials derived from these animal sources in the manufacture of animal or human drug products or biological products should verify that the materials they are using are not derived from animals affected during the contamination incident, or conduct suitable testing of the materials.

This guidance document is being issued as a Level 1 guidance consistent with FDA's good guidance practices (62 FR 8961), February 27, 1997). It is being implemented immediately without prior public comment because of the potential hazard to the public health.

This guidance document may contain collections of information that require OMB clearance under the Paperwork Reduction Act of 1995. FDA will seek such approval and provide an opportunity for comment, as appropriate.

The guidance represents the agency's current thinking on the implications of dioxin/PCB contamination in animal and human drug products and biological 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, regulations, or both.

Interested persons may submit written comments on the draft 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 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.

Dated: August 19, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–22316 Filed 8–26–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0495]

Prescription Drug User Fee Act (PDUFA) II Five-Year Plan Revision; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of an internal planning document entitled ''PDUFA II Five–Year Plan: FY 1999 Revision.'' This revised plan updates FDA's anticipated prescription drug user fee revenues and planned expenditures of the fee revenues over the 5-year period from 1998 to 2002. The revised plan to achieve the new goals for the drug review process under the Prescription Drug User Fee Act of 1992 (PDUFA), which was amended and extended through the year 2002 by the Food and Drug Administration Modernization Act of 1997, takes into account changes in revenue projections and work load based on actual revenue and application receipts in fiscal year (FY) 1998. The amended and extended PDUFA is referred to as PDUFA II.

DATES: Written comments on the revised plan may be submitted at any time and will be considered as the agency makes annual adjustments to the revised plan in the second quarter of each FY.

ADDRESSES: Copies of this revised plan are available on the Internet at ''www.fda.gov/oc/pdufa2/5yrplan.html''. For those without Internet access, single copies of this revised plan may be obtained from the Office of Management and Systems (HFA–20), Attention: Frank P. Claunts, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Please send a self-addressed adhesive label to assist that office in processing your request. Submit written comments on the revised plan to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Frank P. Claunts, Office of Management Systems (HFA–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4427.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of an internal planning document entitled ''PDUFA II Five–Year Plan: FY 1999 Revision.'' PDUFA was amended and

extended through the year 2002 by the Food and Drug Administration Modernization Act of 1997. The amended and extended PDUFA is referred to as PDUFA II. PDUFA II authorizes appropriations and fees that will provide FDA with resources to sustain the drug review staff developed through FY 1997 and to achieve the even more stringent new goals.

The revised plan begins with a statement of purpose, provides background information on PDUFA and a summary of the new goals, and discusses the 10 major assumptions on which the revised plan is based and how those assumptions have changed since the original plan was issued last year. Included is the assumption that this revised plan is dynamic, and it will be reassessed each FY through 2002. This is the first revision of the plan since it was initially published last year. The individual plans of agency components with major PDUFA responsibilities are summarized, followed by a summary of associated expenditures and an agency summary. Attachments include: Estimates of PDUFA fees and revenues, the **Federal Register** notice of December 22, 1998, establishing prescription drug user fee rates for FY 1999, and the revised ''PDUFA II Information Management Five–Year Plan.''

In FDA's continuing efforts to maximize the availability and clarity of information about the agency's review processes and plans, FDA is sharing this revised plan with all who have an interest, and the agency is making it available on the Internet. The agency welcomes comments, and it will consider them in the future as annual adjustments are made to the plan.

Interested persons may submit written comments on the revised plan to the Dockets Management Branch (address above). 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. The revised plan and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 20, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–22311 Filed 8–26–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–295]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the Information collections referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 CFR, Part 1320. The Agency cannot reasonably comply with the normal clearance procedures because public harm is likely to result due to the possibility of Medicare beneficiaries receiving incomplete information. This information is needed to help beneficiaries have and make informed choices about health plans. Research conducted with Medicare beneficiaries in the course of this disenrollment survey development, confirms that beneficiaries want to know the reasons behind the disenrollment rates when selecting a plan and could not make much sense of the rates alone. The reasons for the disenrollments can only be supplied by this survey. In addition, the Balanced Budget Act (BBA) of 1997, requires the calculation and presentation of ''(I) disenrollment rates for Medicare enrollees electing to receive benefits through the plan for the previous 2 years (excluding disenrollment due to death or moving outside the plan's service area)''; and ''(ii) information on Medicare enrollee satisfaction.'' Under the BBA, HCFA is required to provide a wealth of general and plan comparative information to beneficiaries that will help them make more informed health plan choices. This survey will do that.

HCFA is requesting OMB review and approval of this collection by September 27, 1999, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by September 23, 1999. During this 180-day period, we will publish a separate Federal Register notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Collection Request: New Collection;

Title of Information Collection: Medicare CAHPS Disenrollment Survey;

Form No.: HCFA–R–295 (OMB# 0938–NEW);

Use: This survey will be used to collect information from Medicare beneficiaries who have disenrolled from their health plans during the past year. The purpose of this information is to obtain their ratings of their former plans and the reasons why they left. The survey results will be reported to all beneficiaries in print and on the Internet for the purpose of informed choices.;

Frequency: Annually;

Affected Public: Individuals or Households;

Number of Respondents: 90,000;

Total Annual Responses: 72,000;

Total Annual Hours: 23,760.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of Information requirements. However, as noted above, comments on these Information collection and recordkeeping requirements must be