Estimated Total Annual Burden Hours. 180

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W.; Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 to 60 days after publication of this document in the **Federal Register.** Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: ACF Desk Officer.

Dated: August 23, 1999.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 99–22303 Filed 8–26–99; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–2100]

Agency Information Collection Activities; Announcement of OMB Approval; Survey of Manufacturers of Computer-Controlled, Potentially High-Risk Medical Devices Regarding Year 2000 Status

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Study of Manufacturers of Computer-Controlled, Potentially High-Risk Medical Devices Regarding Year 2000 Status'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Stewart Crumpler, Center for Devices and Radiological Health (HFZ–340), 2094 Gaither Rd., Rockville, MD 20850, 301–594–4659, ext. 119.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 2, 1999 (64 FR 36019), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910–0411. The approval expires on January 31, 2000. A copy of the supporting statement for this information collection is available on the Internet at ''http://www.fda.gov/ohrms/dockets''.

Dated: August 19, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–22315 Filed 8–26–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2635]

Draft Guidance for Industry on ANDA's: Blend Uniformity Analysis; 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 ''ANDA's: Blend Uniformity Analysis.'' This draft guidance is intended to provide recommendations to holders of abbreviated new drug applications (ANDA's) on establishing in-process acceptance criteria related to blend uniformity analysis (BUA) for the manufacture of some drug products.

DATES: Written comments may be submitted on the draft guidance by October 26, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Written requests for single copies of the draft guidance for industry should be submitted to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your requests. 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.

FOR FURTHER INFORMATION CONTACT: Devinder S. Gill, Office of Generic Drugs (HFD–623), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5848.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''ANDA's: Blend Uniformity Analysis.'' This draft guidance is intended to provide recommendations on when BUA should be performed. The recommendations, when applicable, apply to original ANDA's and supplemental ANDA's for formulation and process changes.

This level 1 draft 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 BUA for ANDA's. 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 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 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. 99–22317 Filed 8–26–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2777]

Guidance for Industry on Possible Dioxin/PCB Contamination in Drugs and Biological 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 ''Possible Dioxin/PCB

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