

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]

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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]

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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