Addition 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 Service, 370 L'Enfant Promenade, S.W., Washington D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to made 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., Attn: Ms. Wendy Taylor.

Dated: December 29, 1998.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 99–27 Filed 1–4–99; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0213]

Agency Information Collection Activities; Announcement of OMB Approval; Recordkeeping for Electronic Products, Specific Product Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Reporting and Recordkeeping for Electronic Products: Specific Product Requirements'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 6, 1998 (63 FR 53677), 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 0910–0213. The approval expires on December 31, 2001.

Dated: December 24, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–71 Filed 1–4–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1168]

Draft Guidance for Industry on ANDA's: Impurities in Drug Products; 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: Impurities in Drug Products.'' This draft guidance provides recommendations for including information in abbreviated new drug applications (ANDA's) on the reporting, identification, and qualification of impurities in drug products produced from chemically synthesized drug substances for both monograph and nonmonograph drug products.

DATES: Written comments on the draft guidance may be submitted by May 5, 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.'' Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5600 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Devinder S. Gill, Office of Generic Drugs, Center for Drug Evaluation and Research (HFD–623), 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: Impurities in Drug Products.'' This draft guidance provides information for generic drug products on the following: (1) Qualifying degradation products via a comparison with impurities found in the related United States Pharmacopeia (USP) monograph, scientific literature, or innovator material; (2) qualifying degradation products found at higher levels in the generic drug product than found in the related USP monograph, scientific literature, or innovator material; (3) qualifying degradation products that are not found in the related USP monograph, scientific literature, or innovator material; and (4) threshold levels below which qualification is not needed.

This draft level 1 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 the review of impurities in generic drug products produced from chemically synthesized drug substances. 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 may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 24, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–31 Filed 1–4–99; 8:45 am]

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