TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section; [FDA Form Number]	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours Per Response	Total Hours
314.107(c)(4), 314.107(e)(2)(iv), and 314.107(f)	3	2	6	1	6
314.110(a)(5)	41	1.26	52	.50	26
314.120(a)(5)	12	1.16	14	.50	7
314.420	403	1.72	694	61	42,334
Total					2,372,556

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 25, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–1814 Filed 1–27–05; 12:53 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D–0514]

Draft Guidance for Industry on Abbreviated New Drug Applications: Impurities in Drug Substances; Chemistry, Manufacturing, and Controls Information; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''ANDAs: Impurities in Drug Substances; Chemistry, Manufacturing, and Controls Information.'' This draft guidance provides recommendations on what chemistry, manufacturing, and controls information to include regarding the reporting, identification, and qualification of impurities in drug substances produced by chemical synthesis when submitting documentation for an abbreviated new drug application (ANDA), drug master file (DMF), or a supplement to support changes in drug substance synthesis or process.

DATES: Submit written or electronic comments on the draft guidance May 2, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Scott Furness, Center for Drug Evaluation and Research (HFD–640), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5849.

SUPPLEMENTARY INFORMATION:

I. Background

On December 3, 1999, FDA published in the **Federal Register** (64 FR 67917) the guidance for industry entitled ''ANDA's: Impurities in Drug Substances.'' The guidance provided recommendations for including information in ANDAs and supporting DMFs on the content and qualification of impurities in drug substances produced by chemical syntheses.

FDA is announcing the availability of a draft guidance for industry entitled ''ANDAs: Impurities in Drug Substances,'' which revises the December 3, 1999, guidance. The guidance is being revised to update information on listing of impurities, setting acceptance criteria, and qualifying impurities in conformance with the revision of the guidance for industry entitled ''Q3A Impurities in New Drug Substances'' (Q3A(R), published in February 2003). The guidance is also being revised to remove sections of the guidance containing recommendations that are no longer needed because they are addressed in the more recent Q3A(R).

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this draft guidance was approved under OMB Control Nos. 0910–0001 and 0910–0032.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on these topics. 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 and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: January 24, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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