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

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Total					636,436

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

Under table 2 of this document, the number of respondents is based on the number of manufacturers subject to those regulations. Based on information obtained from FDA's database system, there were 303 licensed manufacturers of biological products in FY 2006. However, the number of recordkeepers listed for § 600.12(a) through (e) excluding (b)(2) is estimated to be 112. This number excludes manufacturers of blood and blood components because their burden hours for recordkeeping have been reported under 21 CFR 606.160 in OMB control no. 0910–0116. The total annual records is based on the annual average of lots released (5,291), number of recalls made (1,841), and total number of adverse experience reports received (45,707) in FY 2006. The hours per record are based on FDA experience.

FDA estimates the burden of this recordkeeping as follows:

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
600.12	112	47.24	5,291	32	169,312
600.12(b)(2)	303	6.08	1,841	24	44,184
600.80(i)	88	519.40	45,707	1	45,707
Total					259,203

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

Dated: February 8, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–2890 Filed 2–14–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0095]

Draft Guidance for Industry and Food and Drug Administration Staff; Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Influenza Viruses; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Influenza Viruses.'' FDA is issuing this draft guidance to inform industry and agency staff of its recommendations for analytical and clinical performance studies to support premarket submissions for in vitro diagnostic devices intended for the detection or detection and differentiation of influenza viruses.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by May 15, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled '' Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Influenza Viruses '' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Tamara Feldblyum Center for Devices and Radiological Health (HFZ–440) Food and Drug Administration 2098 Gaither Rd., Rockville, MD 20850 240–276–0715.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance document recommends studies that may be used to establish the analytical and clinical performance of in vitro diagnostic devices (IVDs) for the detection or detection and differentiation of influenza viruses. The document addresses devices that detect either influenza viral antigens or influenza viral genome (protein or nucleic acid), including those for novel influenza viruses in either human specimens or culture isolate. The guidance does not address devices that detect serological response from the host to the viral antigen, nor does it address establishing performance of non-influenza components of multi-analyte or multiplex devices. This guidance document identifies the classification regulations and product codes for existing legally marketed influenza tests

and supplements other FDA documents that discuss the specific contents of premarket submissions.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized will represent the agency's current thinking on establishing the performance characteristics of in vitro diagnostic devices for the detection or detection and differentiation of influenza viruses. 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 and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive ''Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Influenza Viruses,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1638 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets/default.htm*.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations and guidance documents. These collections of information 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 collections of information in 21 CFR part 807 subpart E have been approved under OMB Control No. 0910–0120; the collections of information in 21 CFR parts 50 and 56 have been approved under OMB Control No. 0910–0130; the collections of information in 21 CFR part 814 have been approved under OMB Control No. 0910–0231; the collections of information in 21 CFR part 812 have been approved under OMB Control No. 0910–0078; and the collections of information associated with CLIA waiver submissions and described in the draft guidance document for industry and FDA staff, ''Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications'' have been approved under OMB Control No. 0910–0598.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

Dated: February 11, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–2826 Filed 2–14–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0065 (formerly Docket No. 2005D–0203)]

Guidance for Industry on Safety Testing of Drug Metabolites; 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 ''Safety Testing of Drug Metabolites.'' This guidance provides recommendations to industry on when and how to identify and characterize drug metabolites whose nonclinical toxicity needs to be evaluated. It also provides recommendations on the timing and type of nonclinical studies that should be conducted to investigate the potential for clinical toxicity of drug metabolites. This guidance applies to small molecule nonbiologic drug products under development. This guidance finalizes the draft guidance published on June 6, 2005.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this 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 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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Aisar Atrakchi, Center for Drug Evaluation and Research (HFD–130), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4384, Silver Spring, MD 20993–0002, 301–796–1036.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Safety Testing of Drug Metabolites.'' This guidance addresses drug metabolites of small molecule nonbiologic drug products and does not apply to some cancer products. It applies to drug metabolites that are not adequately evaluated in standard toxicology testing with the parent drug. This can happen if the metabolite is present only in humans or if it is present at higher levels (referred to in the guidance as ''disproportionate drug metabolite'') in humans than in any of the animal toxicology test species. The guidance provides recommendations on the timing and types of nonclinical safety