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

21 CFR Section	Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1210.13	FDA 1994/Tuberculin test	1	1	1	0.5	0.5
1210.14	FDA 1997/Sanitary inspections of plants	8	1	8	2.0	16.0
1210.20	FDA 1993/Application for permit	8	1	8	0.5	4.0
1210.23	FDA 1815/Permits granted on certificates	8	1	8	0.5	4.0
Total						2,425.0

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record-keeping	Total Annual Records	Hours per Record	Total Hours
1210.15	8	1	8	0.05	0.40

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

The estimated number of respondents and hours per response are based on FDA's experience with the import milk permit program and the average number of import milk permit holders over the past 3 years. FDA estimates that 8 respondents will submit approximately 200 Form FDA 1996 reports annually, for a total of 1,600 responses. FDA estimates the reporting burden to be 1.5 hours per response, for a total burden of 2,400 hours.

The Secretary of Health and Human Services has the discretion to allow Form FDA 1815, a duly certified statement signed by an accredited official of a foreign government, to be submitted in lieu of Forms FDA 1994 and 1995. To date, Form FDA 1815 has been submitted in lieu of these forms. Because FDA has not received any Forms FDA 1994 and 1995 in the last 3 years, the agency estimates no more than one will be submitted annually. FDA estimates the reporting burden for each to be 0.5 hours per response for a total burden reporting burden of 0.5 hours each.

FDA estimates that eight respondents will submit one Form FDA 1997 report annually, for a total of eight responses. FDA estimates the reporting burden to be 2.0 hours per response, for a total burden of 16 hours. FDA estimates that eight respondents will submit one Form FDA 1993 report annually, for a total of eight responses. FDA estimates the reporting burden to be 0.5 hours per response, for a total burden of 4 hours. FDA estimates that eight respondents will submit one Form FDA 1815 report annually, for a total of eight responses. FDA estimates the reporting burden to be 0.5 hours per response, for a total burden of 4 hours.

With regard to records maintenance, FDA estimates that approximately eight recordkeepers will spend 0.05 hours annually maintaining the additional pasteurization records required by § 1210.15, for a total of 0.40 hours annually.

No burden has been estimated for the tagging requirement in § 1210.22 because the information on the tag is either supplied by FDA (permit number) or is disclosed to third parties as a usual and customary part of the shipper's normal business activities (type of product, shipper's name and address). Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information. Under 5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

Dated: November 25, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–28692 Filed 12–3–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1999–D–0128] (formerly Docket No. 1999D–2013)

Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics,'' dated November 2008. The guidance document provides information concerning cooperative manufacturing arrangements applicable to biological products subject to licensure under the U.S. Public Health Service Act (PHS Act). The guidance describes the licensing strategies for meeting the increased need for flexible manufacturing arrangements. The guidance announced in this notice finalizes the draft guidance of the same title.

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

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and

Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, or the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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*.

FOR FURTHER INFORMATION CONTACT: Brenda R. Friend, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210; or

David Cummings, Center for Drug Evaluation and Research (HFD–354), Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 21, rm. 3525, Silver Spring, MD 20993, 301–796–2400.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics'' dated November 2008. The guidance document provides information concerning the various cooperative manufacturing arrangements used in the production of biological products subject to licensure under section 351 of the PHS Act (42 U.S.C. 262). The guidance describes FDA's current thinking on licensing strategies for meeting the increased need for planning flexible manufacturing arrangements. Because cooperative manufacturing arrangements can take a considerable amount of time to develop, the guidance may also be useful for planning purposes in the early phases of product development. Several types of manufacturing arrangements discussed in the guidance include short supply arrangements, divided manufacturing arrangements, shared manufacturing arrangements, and contract manufacturing arrangements. The guidance supersedes ''FDA's Policy Statement Concerning Cooperative Manufacturing Arrangements for Licensed Biologics'' published in the **Federal Register** of November 25, 1992 (57 FR 55544).

In the **Federal Register** of August 3, 1999 (64 FR 42136), FDA announced the availability of the draft guidance of the same title dated August 1999. FDA received several comments on the draft guidance; those comments were considered as the guidance was finalized. In response to public comments, we clarified the document and reformatted it into plain language. In the **Federal Register** of July 23, 2007 (72 FR 40157), FDA published a 60-day notice requesting public comment on the information collections in the draft guidance of the same title dated July 2007, which revised the draft guidance dated August 1999. The guidance announced in this notice finalizes the draft guidance dated July 2007.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. 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. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this guidance were approved under OMB control number 0910–0629.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this guidance. 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 the brackets in the heading of this document. A copy of the 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.regulations.gov*.

Dated: November 24, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0043]
[FDA No. 225–08–8006]

Memorandum of Understanding Between the Food and Drug Administration and WebMD, LLC

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA's Office of External Relations and WebMD, LLC. The purpose of the MOU is to extend the reach of FDA Consumer Health Information and to provide consumers with better information and timely content concerning public health and safety topics, including alerts of emerging safety issues and product recalls.

Specific elements of the MOU include the creation of an FDA/WebMD online resource on the WebMD.com site, which will feature editorial and visual FDA Consumer Health Information, and the inclusion of FDA Consumer Health Information in at least three issues per year of *WebMD The Magazine*.

An agency policy statement summarizing the criteria and processes for development of this type of collaboration is available on FDA's Web site at *www.fda.gov/consumer/co_brandpolicy.html*.

DATES: The agreement became effective October 10, 2008.

FOR FURTHER INFORMATION CONTACT: Jason Brodsky, Director, Consumer Health Information Staff, Office of External Relations (HFI–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6251

Nan Forte, Executive Vice President,