

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 1999D-2013]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910-NEW and title "Draft Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Draft Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics—(OMB Control Number 0910-NEW)

The draft guidance document, when finalized, will provide information concerning cooperative manufacturing arrangements applicable to biological products subject to licensure under section 351 of the U.S. Public Health Service Act. The draft guidance addresses several types of manufacturing arrangements (i.e., short supply arrangements, divided manufacturing arrangements, shared manufacturing arrangements, and contract manufacturing arrangements) and describes certain reporting and recordkeeping responsibilities, associated with these arrangements, for the licensed manufacturer(s), contract manufacturer(s), and final product manufacturer(s) including the following: (1) Notification of any proposed change in the product, production process, quality controls or facilities; (2) notification of results of tests and investigations related to or impacting the product; (3) notification of products manufactured in a contract facility; and (4) standard operating procedures.

A. Notification of Any Proposed Change in the Product, Production Process, Quality Controls or Facility

Each licensed manufacturer in a divided manufacturing arrangement or shared manufacturing arrangement must notify the appropriate FDA Center

regarding proposed changes in the manufacture, testing, or specifications of its product, in accordance with § 601.12 (21 CFR 601.12). In the draft guidance, we recommend that each licensed manufacturer that proposes such a change should inform other participating licensed manufacturer(s) of the proposed change.

For contract manufacturing arrangements, we recommend that the contract manufacturer should share with the license manufacturer all important proposed changes to production and facilities (including introduction of new products or at inspection). The license holder is responsible for reporting these changes to FDA (§ 601.12).

B. Notification of Results of Tests and Investigations Related to or Impacting the Product

In the draft guidance, we recommend the following for contract manufacturing arrangements:

- The contract manufacturer should fully inform the license manufacturer of the results of all tests and investigations regarding or possibly having an impact on the product; and
- The license manufacturer should obtain assurance from the contractor that any FDA list of inspectional observations will be shared with the license manufacturer to allow evaluation of its impact on the purity, potency, and safety of the license manufacturer's product.

C. Notification of Products Manufactured in a Contract Facility

In the draft guidance, we recommend for contract manufacturing arrangements that a license manufacturer cross reference a contract manufacturing facility's Master Files only in circumstances involving certain proprietary information of the contract manufacturer such as a list of all

products manufactured in a contract facility. In this situation the license manufacturer should be kept informed of the types or categories of all products manufactured in the contract facility.

D. Standard Operating Procedures

In the draft guidance, we remind the license manufacturer that the license manufacturer assumes responsibility for compliance with the applicable product and establishment standards (§ 600.3(t)) (21 CFR 600.3(t)). Therefore, if the license manufacturer enters into an agreement with a contract manufacturing facility, the license manufacturer must ensure that the facility complies with the applicable standards. An agreement between a license manufacturer and a contract manufacturing facility normally includes procedures to regularly assess the contract manufacturing facility's compliance. These procedures may include, but are not limited to, review of records and manufacturing deviations and defects, and periodic audits.

For shared manufacturing arrangements, each manufacturer must submit a separate biologics license application describing the manufacturing facilities and operations applicable to the preparation of that manufacturer's biological substance or product (§ 601.2(a)) (21 CFR 601.2(a)). In this draft guidance, we expect the manufacturer that prepares (or is responsible for the preparation of) the product in final form for commercial distribution to assume primary responsibility for providing data demonstrating the safety, purity, and potency of the final product. We also expect the licensed finished product manufacturer to be primarily responsible for any postapproval obligations, such as postmarketing clinical trials, additional product stability studies, complaint handling, recalls, postmarket reporting of the dissemination of advertising and promotional labeling materials as required under § 601.12(f)(4) and adverse

experience reporting. We recommend that the final product manufacturer establish a procedure with the other participating manufacturer(s) to obtain information in these areas.

Description of Respondents: The recordkeeping and reporting recommendations described in this document affect the participating licensed manufacturer(s), final product manufacturer(s), and contract manufacturer(s) associated with cooperative manufacturing arrangements.

Burden Estimate: We believe that the information collection provisions in the draft guidance do not create a new burden for respondents. We believe the reporting and recordkeeping provisions are part of usual and customary business practice. Licensed manufacturers would have contractual agreements with participating licensed manufacturers, final product manufacturers, and contract manufacturers, as applicable for the type of cooperative manufacturing arrangement, to address all these information collection provisions.

This draft guidance also refers to previously approved collections of information found in FDA regulations at parts 201, 207, 211, 600, 601, 606, 607, 610, 660, 803, and 807 (21 CFR parts 201, 207, 211, 600, 601, 606, 607, 610, 660, 803, and 807). The collections of information in §§ 606.121, 606.122, and 610.40 have been approved under OMB Control No. 0910–0116; § 610.2 has been approved under OMB Control No. 0910–0206; §§ 600.12(e) and 600.80 have been approved under OMB Control No. 0910–0308; §§ 601.2(a), 601.12, 610.60, 610.61, 610.62, 610.67, 660.2(c), 660.28(a) and (b), 660.35(a), (c) through (g), and (i) through (m), 660.45, and 660.55(a) and (b) have been approved under OMB Control No. 0910–0338; §§ 803.20, 803.50, and 803.53 have been approved under OMB Control No. 0910–0437; and §§ 600.14 and 606.171 have been approved under OMB Control No. 0910–0458. The current

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good manufacturing practice regulations for finished pharmaceuticals (part 211) have been approved under OMB Control No. 0910–0139; the establishment registration regulations (parts 207, 607, and 807) have been approved under OMB Control Nos. 0910–0045, 0910–0052, and 0910–0387; and the labeling regulations (part 201) have been approved under OMB Control Nos. 0910–0340 and 0910–0370.

In the **Federal Register** of July 23, 2007 (72 FR 40157), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received on the information collection.

Dated: NOV 13 2007
November 13, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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