

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D-0083]

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Author D. Hawkins

Draft Guidance for Industry on Clinical Data Needed to Support the Licensure of Trivalent Inactivated Influenza Vaccines; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Clinical Data Needed to Support the Licensure of Trivalent Inactivated Influenza Vaccines," dated March 2006. The draft guidance document is intended to provide to sponsors of trivalent inactivated influenza vaccines guidance on the clinical data needed to support a Biologics License Application (BLA). The draft guidance summarizes clinical development approaches to facilitate and expedite the licensure of new trivalent inactivated influenza vaccines and addresses both traditional and accelerated approval.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 90 days after date of publication in the Federal Register*] to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug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.
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Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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*.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Guidance for Industry: Clinical Data Needed to Support the Licensure of Trivalent Inactivated Influenza Vaccines," dated March 2006. The draft guidance is intended to provide to sponsors of trivalent inactivated influenza vaccines guidance on the clinical data needed to support a BLA. The draft guidance summarizes clinical development approaches to facilitate and expedite the licensure of new "split virus" trivalent inactivated influenza vaccines and addresses both traditional and accelerated approval. The approaches are also applicable to vaccines made with other manufacturing processes; e.g., whole virus inactivated, cell-culture based inactivated, recombinant protein, and adjuvanted influenza vaccines. The draft guidance does not address live attenuated influenza vaccines or influenza vaccines that do not contain a hemagglutinin component. The draft guidance also does not address the

nonclinical development of investigational vaccines, or the chemistry, manufacturing, control, or inspection of the manufacturing facility needed for licensure. -

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. 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 information collection provisions in this guidance for 21 CFR part 601 have been approved under OMB control number 0910-0338.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft 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 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.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 2/28/06
February 28, 2006.



Jeffrey Sauren,
Assistant Commissioner for Policy.

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