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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1400]

Draft "Guidance for Industry: Considerations for Reproductive Toxicity Studies for Preventive Vaccines for Infectious Disease Indications;" 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: Considerations for Reproductive Toxicity Studies for Preventive Vaccines for Infectious Disease Indications" dated August 2000. The draft guidance document provides information to sponsors regarding assessment of the reproductive toxicity potential of preventive vaccines for infectious diseases. The draft guidance document, when finalized, is intended to provide sponsors with guidance for the conduct of reproductive toxicity studies for preventive vaccines and to consider establishing clinical pregnancy registries for preventive vaccines indicated for females of childbearing potential and pregnant individuals.

DATES: Submit written comments on the draft guidance to ensure their adequate consideration in preparation of the final document by [*insert date 90 days after date of publication in the Federal Register*].

ADDRESSES: Submit written requests for single copies of "Guidance for Industry: Considerations for Reproductive Toxicity Studies for Preventive Vaccines for Infectious Disease Indications" 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, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice cb9911

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Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Astrid L. Szeto, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

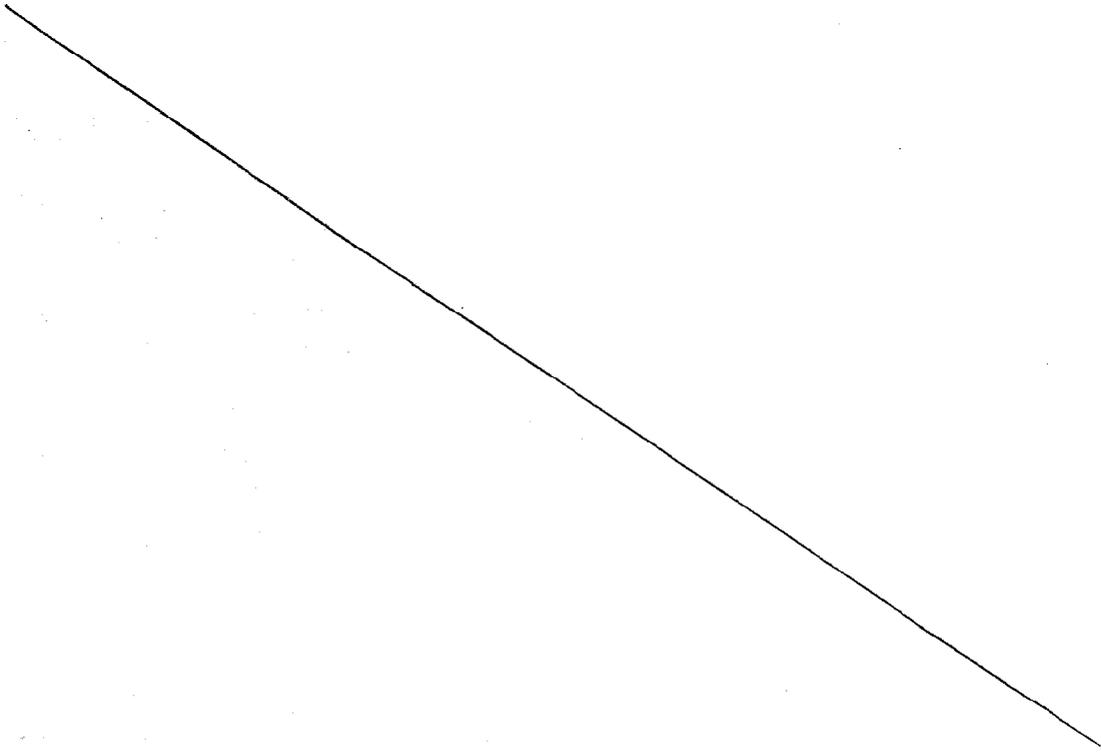
FDA is announcing the availability of a draft guidance document entitled "Guidance for Industry: Considerations for Reproductive Toxicity Studies for Preventive Vaccines for Infectious Disease Indications" dated August 2000. Pre-clinical reproductive toxicity studies of vaccines intended for maternal immunization and/or females of child bearing age are critical in assessing the potential for the developmental toxicity of the product. However, the performance and design of pre-clinical reproductive toxicity studies for vaccines to support their use in females of childbearing potential and/or for maternal immunization have not been addressed in the scientific literature. This draft guidance document would provide general and specific considerations that should be taken into account in the assessment of reproductive toxicity for preventive vaccines, and in establishing clinical pregnancy registries for vaccine products post-licensure. The draft guidance document does not address concerns regarding male reproductive toxicity and fertility studies.

This draft guidance document represents the agency's current thinking with regard to the performance and design of pre-clinical reproductive toxicity studies for vaccines. 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

statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

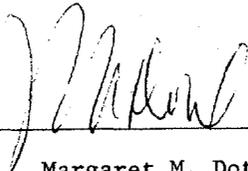
This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Submit written comments to ensure adequate consideration in preparation of the final document by [*insert date 90 days after date of publication in the Federal Register*]. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the draft guidance document at <http://www.fda.gov/cber/guidelines.htm>.

Dated: 8/15/00
August 15, 2000



Margaret M. Dotzel
Associate Commissioner for Policy

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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