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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 99D-2096]

**Draft "Guidance for Industry: Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations;" Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations." The draft guidance document is intended to provide sponsors and manufacturers FDA's current thinking on the criteria by which two monoclonal antibody products would be considered the same under the Orphan Drug Act and implementing regulations.

**DATES:** Written comments may be submitted at any time, however, comments should be submitted by (*insert date 90 days after date of publication in the Federal Register*), to ensure their adequate consideration in preparation of the final document.

**ADDRESSES:** Submit written requests for single copies of "Guidance for Industry: Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations" to the Office of Communication, Training, and Manufacturers Assistance (HFM-940), 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 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance. 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:** Stephen M. Ripley, 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 document entitled “Guidance for Industry: Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations.”

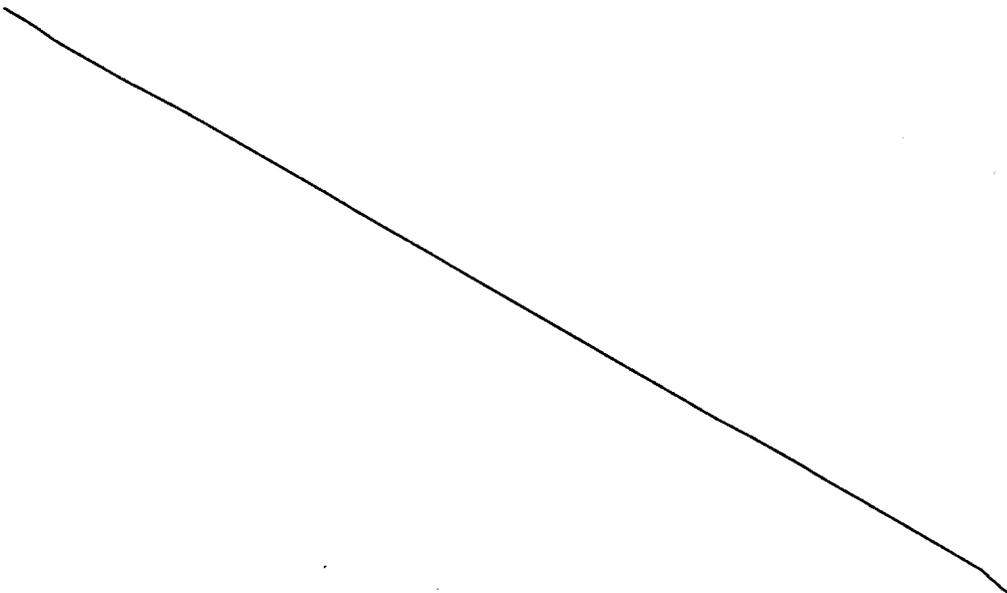
In the **Federal Register** of December 29, 1992 (57 FR 62076), FDA published the orphan drug regulations final rule. The final rule established in part 316 (21 CFR part 316) regulations that prescribe certain incentives for the development of “orphan drugs,” drugs which are intended for use in rare diseases or conditions. One of the incentives for orphan drug development is to obtain exclusive approval for the pioneer product for a period of 7 years during which no approval will be given to a subsequent sponsor of the same drug product for the same indication unless it proves to be clinically superior, as defined in § 316.3(b)(3). In determining whether or not two products would be considered the same, FDA recognized that different criteria were necessary for macromolecules versus small molecules (§ 316.3(b)(13)). Macromolecules include a variety of structures including proteins, nucleic acids, carbohydrates and closely related, complex, partly definable drugs such as vaccines or surfactants. The current definition of sameness for protein drugs (§ 316.3(b)(13)(ii)(A)) however, does not consider the unique nature of antibodies. The draft document is intended to describe FDA’s thinking on the criteria by which two monoclonal antibody products would be considered the same under the Orphan Drug Act and its implementing regulations.

This draft guidance document represents the agency’s current thinking on the interpretation of the orphan drug regulations as they pertain to monoclonal antibodies. It does not create or

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

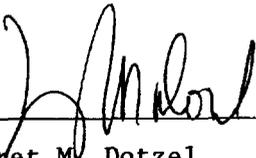
This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by (insert date 90 days after date of publication in the **Federal Register**), to ensure adequate consideration in preparation of the final document. 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 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 document using the World Wide Web (WWW). For WWW access, connect to CBER at "http://www.fda.gov/cber/guidelines.htm".

Dated: 7/14/99  
July 14, 1999

  
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Margaret M. Dotzel  
Acting Associate Commissioner for Policy

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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**CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL**

