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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 99D-1718]

**Draft Guidance for Industry on Monoclonal Antibodies Used as Reagents in Drug Manufacturing; Availability**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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Monoclonal Antibodies Used as Reagents in Drug Manufacturing." This draft guidance provides recommendations to sponsors and applicants on the information that should be included in investigational new drug applications (IND's), new drug applications (NDA's), abbreviated new drug applications (ANDA's), biologics license applications (BLA's), and supplements to these applications when monoclonal antibodies are used as reagents in the manufacture of drug substances and drug products that are regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

**DATES:** Written comments on the draft guidance document may be submitted by *(insert date 90 days after date of publication in the Federal Register)*. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Copies of this draft guidance are available on the Internet at "<http://www.fda.gov/cder/guidance/index.htm>" or "<http://www.fda.gov/cber/guidelines.htm>". Submit written requests for single copies of the draft guidance for industry to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, 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. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Eugenia M. Nashed, Office of New Drug Chemistry (HFD-570), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1050, or

Kurt A. Brorson, Office of Therapeutics Research and Review (HFM-561), Center for Biologics Evaluation and Research, 8800 Rockville Pike, Bethesda, MD 20892-0029, 301-827-0661.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of a draft guidance for industry entitled "Monoclonal Antibodies Used as Reagents in Drug Manufacturing." This draft guidance focuses on chemistry, manufacturing, and control issues relating to the use of monoclonal antibodies as reagents in drug substance and drug product manufacture that should be addressed in IND's, NDA's, ANDA's, BLA's, and supplements to these applications.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on monoclonal antibodies used as reagents. 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.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number

