identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

### III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: September 9, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03–23508 Filed 9–12–03; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2002D–0094]**

### Guidance for Industry on Investigational New Drug Application Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer.'' This guidance clarifies FDA's policy on exemption from investigational new drug application (IND) requirements for studies of marketed cancer drug or biological products. This guidance is intended to decrease the submission of unnecessary IND exemptions.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or 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 that office in processing your requests. This guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. Submit written comments on the 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Grant A. Williams, Center for Drug Evaluation and Research (HFD–150), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5758, or

Patricia Keegan, Center for Biologics Evaluation and Research (HFM–573), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5093.

**SUPPLEMENTARY INFORMATION:**

### I. Background

FDA is announcing the availability of a guidance for industry entitled ''IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer.'' Exemption from IND regulation of certain studies of marketed drugs is allowed under 21 CFR 312.2(b)(1). Along with other criteria outlined in the regulation, investigations that involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product are not exempt from the requirements for an IND. This guidance discusses the pertinent regulations relating to exemption of INDs, the risk/benefit determination in the practice of oncology, FDA's policy for determining exemption status based on risk, and specific examples of studies generally considered exempt.

In the **Federal Register** of April 9, 2002 (67 FR 17078), FDA announced the availability of a draft version of this guidance and gave interested persons an opportunity to submit comments through June 10, 2002. The agency received comments from investigators at two institutions and took the comments into consideration when finalizing the guidance. However, the final guidance includes no substantive changes, only editorial and clarifying changes.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on IND exemptions based on risk for studies of lawfully marketed cancer drug or biological products. 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 requirements of the applicable statutes and regulations.

### II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The 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.

### III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: September 5, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03–23510 Filed 9–12–03; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2003D–0399]**

### Guidance for Industry on Pentetate Calcium Trisodium and Pentetate Zinc Trisodium for Treatment of Internal Contamination with Plutonium, Americium, or Curium; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that we (FDA) have concluded that pentetate calcium trisodium (Ca-DTPA) and pentetate zinc trisodium (Zn-DTPA), when produced under conditions specified in approved new drug applications (NDAs), can be found