application (NDA) 21–487, memantine hydrochloride, Forest Laboratories, Inc., indicated for the treatment of moderate to severe dementia of the Alzheimer's type. On September 25, 2003, the committee will discuss supplementary new drug application 20–717 /S–008 Provigil (modafinil) Tablets, Cephalon, Inc., indicated for use to improve wakefulness in patients with excessive sleepiness associated with disorders of sleep and wakefulness.

This notice is given under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: September 8, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–23333 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–0412]

International Conference on Harmonisation; Draft Guidance on E2D Postapproval Safety Data Management: Definitions and Standards for Expedited Reporting; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''E2D Postapproval Safety Data Management: Definitions and Standards for Expedited Reporting.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance provides definitions associated with postapproval product safety information and standards for collecting and expedited reporting of safety information to the regulatory authorities. The draft guidance is intended to harmonize internationally the collection and management of postapproval product safety data.

DATES: Submit written or electronic comments on the draft guidance by October 20, 2003.

ADDRESSES: Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857;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, 301–827–3844, FAX: 888–CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your requests. 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.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Susan Lu, Center for Drug Evaluation and Research (HFD–430), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1514; or Tim Cote, Center for Biologics Evaluation and Research (HFM–224), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6088.

Regarding the ICH: Janet Showalter, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0865.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are: The European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research; FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada's Health Products and Food Branch, and the European Free Trade Area.

In July 2003, the ICH Steering Committee agreed that a draft guidance entitled ''E2D Postapproval Safety Data Management: Definitions and Standards for Expedited Reporting'' should be made available for public comment. The draft guidance is the product of the Efficacy Expert Working Group of the ICH. Comments about this draft guidance will be considered by FDA and the Efficacy Expert Working Group.

In the **Federal Register** of March 1, 1995 (60 FR 11284), FDA published the ICH guidance entitled ''E2A Clinical Safety Data Management: Definitions and Standards for Expedited Reporting,'' which provides guidance on preapproval safety data management. This ICH E2D draft guidance is based on the content of ICH E2A and provides further guidance on definitions associated with postapproval product safety information and standards for collecting and expedited reporting of safety information to the regulatory authorities.

This draft guidance, when finalized, will represent the agency'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 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 draft guidance. 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 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