

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.

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International Conference on Harmonisation; Draft Guidance on E2D Postapproval Safety Data Management: Definitions and Standards for Expedited Reporting; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "E2D Postapproval Safety Data Management: Definitions and Standards for Expedited Reporting." The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use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 The draft guidance provides definitions associated with postapproval product safety information and standards for collecting and expedited reporting of safety information to the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 The draft guidance is intended to harmonize internationally the collection and management of postapproval product safety data.

DATES: Submit written or electronic comments on the draft guidance by October 20, 2003.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