ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled, ''Guidance for Industry: FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products.'' The draft guidance considers the quality and quantity of data that may be adequate to add a new use to the prescribing information for a product used in the treatment of cancer. The draft guidance is part of the agency's ''New Use Initiative—Evidence for Primary and Supplemental Approvals,'' which is exploring ways to expedite the development of new and supplemental uses for drug and biological products. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a draft guidance that discusses what clinical evidence of efficacy should be provided in new drug and biological product license applications as well as in supplemental applications. The agency is seeking public comment on the draft guidance.

DATES: Written comments on the draft guidance by May 20, 1997. General comments on agency guidance documents may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Guidance for Industry: FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products'' to the Drug Information Branch (HFD–210), 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 two self-addressed adhesive labels to assist the offices in processing your requests. The draft guidance also may be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by facsimile by calling the FAX Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert J. Delap, Center for Drug Evaluation and Research (HFD–150), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2473.

SUPPLEMENTARY INFORMATION:

I. Background

When drugs approved for one use prove safe and effective for treating other conditions, information on the new use should be added to the product labeling as soon as possible. FDA has launched the ''New Use Initiative—Evidence for Primary and Supplemental Approvals'' to explore ways the agency can improve the supplemental application process. FDA believes it can expedite the development of new and supplemental uses of drug and biological products by doing the following: (1) Clarifying what evidence should be provided in primary as well as supplemental applications and (2) working with industry to reduce barriers to submitting applications for new uses for their products.

Some of the information submitted in a supplemental application may be available from the primary application. As a result, the agency decided that its first step would be to clarify what information sponsors should provide in applications in general. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance entitled ''Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products,'' The draft guidance addresses the information that should be provided in new drug and biological product license applications as well as supplemental applications.

The draft guidance entitled ''Guidance for Industry: FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products'' focuses on the particular information to be provided when submitting an application for the approval of a supplemental new use for a drug product to treat cancer. Cancer treatments often yield potential new uses for already marketed drugs.

Although this draft guidance does not create or confer any rights on any person, and does not operate to bind FDA in any way, it does represent the agency's current thinking on new cancer treatment uses for marketed drug and biological products.

II. Request for Comments

Interested parties 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 found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

An electronic version of the draft guidance also is available via Internet using the World Wide Web (WWW) (connect to the CDER home page at attp://www.fda.gov/cder and go to the ''Regulatory Guidance'' section, or to the CBER home page at http://www.fda.gov/cber/cberfp.html).

Dated: March 14, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–7132 Filed 3–20–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 97D–0100]

Draft Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products; 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, ''Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products.'' The purpose of the draft guidance is to clarify what clinical evidence of effectiveness should be provided in new drug applications, biological product license applications, and supplemental applications. The draft guidance is part of the agency's ''New Use Initiative—Evidence for Primary and Supplemental Approvals,'' which is exploring ways to expedite the development of new and supplemental uses for drug and biological products. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance that discusses the quality and quantity of data that may be adequate to add a new use to the prescribing information for a product used in the treatment of cancer. The agency is seeking public comment on the draft guidance.

DATES: Written comments on the draft guidance by May 20, 1997. General comments on agency guidance documents may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Guidance for Industry:

Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products'' to the Drug Information Branch (HFD–210), 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 two self-addressed adhesive labels to assist the offices in processing your requests. The draft guidance also may be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by facsimile by calling the FAX Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joseph P. Griffin, Center for Drug Evaluation and Research (HFD–5), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400.

SUPPLEMENTARY INFORMATION:

I. Background

When drugs approved for one use prove safe and effective for treating other conditions, information on the new use should be added to the product labeling as soon as possible. FDA is exploring ways to expedite the development of new and supplemental uses of drug and biological products. The agency believes it can improve the approval process and increase the number of safe and effective new uses being added to drug labeling by doing the following: (1) Clarifying what evidence should be provided in primary and supplemental applications and (2) working with industry to reduce barriers to submitting applications for new uses for their products.

Because some of the information submitted in a supplemental application may be available from the primary application, the agency decided that its first step would be to clarify what information sponsors should provide in applications in general. The draft guidance entitled, ''Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products'' discusses the clinical evidence that should be provided when submitting a new drug or biological product license application or a supplemental application for a new use of a drug or biological product.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a second draft guidance entitled, ''Guidance for Industry: FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products.'' The draft guidance focuses on the quality and quantity of data that may be adequate to add a new use to the prescribing information for a product used in the treatment of cancer. Cancer treatments often yield potential new uses for marketed drug products.

Although this guidance does not create or confer any right on any person , and does not operate to bind FDA in any way, it does represent the agency's current thinking on clinical evidence of effectiveness for human drug and biological products.

II. Request for Comments

Interested parties 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 found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

An electronic version of this draft guidance also is available via Internet using the World Wide Web (WWW) (connect to the CDER home page at http://www.fda.gov/cder and go to the ''Regulatory Guidance'' section, or to the CBER home page at http://www.fda.gov/cber/cberftp.html).

Dated: March 14, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–7133 Filed 3–20–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0095]

Hoffmann-La Roche, Inc., et al.; Withdrawal of Approval of 49 New Drug Applications, 9 Abbreviated Antibiotic Applications, and 36 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of March 27, 1996 (61 FR 13506). The document announced the withdrawal of approval of 49 new drug applications (NDA's), 9 abbreviated antibiotic applications (AADA's), and 36 abbreviated new drug applications (ANDA's). The document inadvertently withdrew approval of NDA 18–962 for Manganese Chloride Injection held by Abbott Laboratories, D–389, Bldg. AP30, 200 Abbott Park Rd., Abbott Park, IL 60064–3537. This document confirms that approval of NDA 18–962 is still in effect, and that the withdrawal of approval of the NDA was in error.

EFFECTIVE DATE: March 27, 1996.

FOR FURTHER INFORMATION CONTACT: Olivia A. Vieira, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1046.

In FR Doc. 96–7309, appearing on page 13506 in the **Federal Register** of Wednesday, March 27, 1996, the following correction is made: On page 13507, in the table, the entry for NDA 18–962 is removed.

Dated: March 14, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–7187 Filed 3–20–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket Nos. 96E–0289, 96E–0286, and 96E–0288]

Determination of Regulatory Review Period for Purposes of Patent Extension; DAUNOXOME®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for DAUNOXOME® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.