

B. Deadlines

The applications shall be considered as meeting the deadline if they are either:

1. Received on or before the deadline date, or
2. Sent on or before the deadline date and received in time for submission to the review group. (Applicants should request a legibly-dated U.S. Postal Service postmark or obtain a legibly-dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late Applications

Applications which do not meet the criteria in either paragraph 1 or 2 immediately above are considered late applications and will not be considered in the current competition and will be returned to the applicant.

D. Reviews

Applications are not subject to review as governed by Executive Order 12372, Intergovernmental Review of Federal Programs.

Review Criteria**A. Initial Applications**

Applications will be reviewed and evaluated based on the evidence submitted which specifically describes the applicant's ability to meet the following criteria:

1. Adequacy and completeness of the project plan and methodology, including a description of:
 - a. The requirements, problems, objectives, complexities, and interactions required of this cooperative agreement.
 - b. How closely objectives of the proposal fit the objectives for which applications were invited.
 - c. Project development and implementation including action steps and time frames.
 - d. How surveillance, planning, epidemiologic evaluation, and coordinating activities will be conducted.
 - e. How project baseline data will be collected.
 - f. How specific intervention strategies aimed at reducing morbidity and mortality in the targeted population will be formulated, implemented, and evaluated.
2. Qualifications and adequacy of time allocation of the applicant's existing staff and staff to be assigned to this project and the facilities, capabilities, office space, necessary equipment, and support staff resources available for the performance of this project.

3. Documentation that the area covered by the application encompasses a defined population and focuses on a population which meets the following:

- a. Sample is drawn from a population of at least 1.5 million in an urban area with a wide range of socio-economic levels and diverse racial and ethnic groups.
- b. Area chosen need not necessarily represent a complete jurisdiction (e.g., a State or city) but must be population-based (i.e., encompass a definable population).
- c. Applicant resources must include available census and vital data and an ongoing cancer registry or the commitment and potential to establish this necessary registry.
4. The soundness of proposed methods to achieve objectives and of the evaluation plan to monitor effectiveness.
5. Explanation of budget request including justification for individual budget items.

B. Continuation Applications

1. A continuation application within the project period will be made on the basis of the following criteria:
 - a. The accomplishment of the current budget period should show that the applicant is meeting its objectives:
 - b. The objectives for the new budget period are realistic, specific, and measurable:
 - c. The methods described will clearly lead to the achievement of these objectives:
 - d. The evaluation plan will allow management to monitor whether the methods are effective in achieving objectives:
 - e. The budget request is clearly explained, adequately justified, reasonable, and consistent with the intended use of the cooperative agreement funds.

Content of Application

Applicants Are Required To Include a Narrative Which Must

- A. Describe the applicant's understanding of the requirements, problems, objectives, complexities, and interactions required of this cooperative agreement.
- B. Describe how the applicant will develop and implement this project including a time schedule.
- C. Document the ability to provide the staff, knowledge, and resources to perform their part of this project, and describe the approach to be used in carrying out their responsibilities.
- D. Identify and provide the qualifications and time allocations of

the existing staff and staff to be assigned to this project, and the facilities/capabilities, office space, necessary equipment, and support staff resources available for the performance of this project.

E. Specify how the project will be administered, including the organizational structure.

F. Describe plans to publish results and designate responsibilities for scientific publications and authors, summary documents, news releases, etc.

Information

Information on application procedures, copies of application forms, and other material may be obtained from: Mr. Luther DeWeese, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road NE., Room 321, Atlanta, Georgia 30305, (404) 262-6575 or FTS 236-6575.

Technical assistance may be obtained from the Division of Chronic Disease Control:

Marion Nadel, Ph.D., Health Scientist, Cancer Branch, Division of Chronic Disease Control, Center for Environmental Health, Centers for Disease Control, Atlanta, Georgia 30333, (404) 452-4068 or FTS 236-4068.

Richard B. Rothenberg, M.D., Assistant Director for Science, Division of Chronic Disease Control, Center for Environmental Health, Centers for Disease Control, Atlanta, Georgia 30333, (404) 452-4251 or FTS 236-4251.

Dated: June 11, 1986.

Robert L. Foster,

Acting Director, Office of Program Support, Centers for Disease Control.

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BILLING CODE 4160-18-M

Food and Drug Administration

(Docket No. 86N-0229)

Removal of Nomifensine Maleate From List of Approved Drug Products

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing both its determination that nomifensine maleate was withdrawn from sale by its manufacturer for reasons of safety, and the removal of nomifensine maleate from the publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the list). The list is a requirement under the Drug Price Competition and Patent Term

Restoration Act of 1984. Nomifensine maleate is an antidepressant drug that was marketed under the trade name Merital.

DATE: The drug nomifensine maleate was removed from the approved drug products list effective March 19, 1986.

FOR FURTHER INFORMATION CONTACT: Carol Kimbrough, Center for Drugs and Biologics (HFN-364), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8046.

SUPPLEMENTARY INFORMATION: On September 24, 1984, the President signed into law the Drug Price Competition and Patent Term Restoration Act (the 1984 amendments), which amends the Federal Food, Drug, and Cosmetic Act (the act) and requires, among other things, FDA to make publicly available a list, supplemented monthly, of drug products approved as safe and effective for marketing. One use of the list is as a source of information on drugs that are eligible for agency approval on the basis of abbreviated new drug applications (ANDA's). Section 505(j)(6)(C) of the act (21 U.S.C. 335(j)(6)(C)), added by the 1984 amendments, requires FDA to immediately remove from the list any drug that the agency determines was withdrawn from sale for safety or effectiveness reasons. Once removed from the list, the drug is no longer eligible for approval on the basis of ANDA's.

In implementing the 1984 amendments, the agency satisfied the requirement for a publicly available list of approved drugs by modifying and supplementing a regular agency publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," popularly known as "the Orange Book." The current edition (1985, 6th edition) of that publication contains an entry on page 3-155 for nomifensine maleate, 25 milligram (mg) and 50 mg capsules, approved for marketing by Hoechst-Roussel Pharmaceuticals, Inc. (Hoechst-Roussel). No other nomifensine maleate products are approved for marketing.

On January 23, 1986, Hoechst-Roussel announced that it was immediately withdrawing nomifensine maleate (trade name, Merital) from sale in the United States and on a worldwide basis. The manufacturer stated that the voluntary withdrawal was being undertaken as a precautionary measure because of an increase in the number of reports of serious hypersensitivity reactions,

notably hemolytic anemia, occurring in nomifensine-treated patients in the United Kingdom. (The hemolytic anemia side effect is included in the product's approved labeling.)

Communications between the FDA staff and Hoechst-Roussel confirmed that the manufacturer's decision to withdraw the product from sale was based on safety concerns. As a consequence, the Director of the Center for Drugs and Biologics determined that under section 505(j)(6)(C) of the act, nomifensine maleate should be removed from the list of approved drugs that the agency is required to maintain. (The 25 mg nomifensine maleate product on the list was never marketed in the United States. However, for purposes of implementation of section 505(j)(6)(C) of the act, the agency is deeming the circumstances of the withdrawal from marketing of the 50 mg product to include constructive withdrawal of the 25 mg product as well.) This change, effective on March 19, 1986, was indicated in the most recent Orange Book supplement, cumulative supplement 7, August 1985 to March 1986. As a consequence of the removal, ANDA's will not be accepted for the drug.

Dated: June 10, 1986.

John M. Taylor,
Acting Associate Commissioner for
Regulatory Affairs.

(FR Doc. 86-13573 Filed 6-16-86; 8:45 am)

BILLING CODE 4160-01-M

(Docket No. 86M-0206)

**Travenol-Genentech Diagnostics;
Premarket Approval of GammaDab[®]
[¹²⁵I] Alpha-Fetoprotein
Radioimmunoassay Kit (for Use as an
Aid in the Detection of Fetal Open
Neural Tube Defects)**

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Travenol-Genentech Diagnostics, Cambridge, MA, for premarket approval, under the Medical Device Amendments of 1976, of the GammaDab[®] [¹²⁵I] Alpha-Fetoprotein Radioimmunoassay Kit (for use as an aid in the detection of fetal open neural tube defects). After reviewing the recommendation of the Immunology Devices Panel, DFA's Center for Devices and Radiological Health (CDRH) notified the applicant of the approval of the application.

DATE: Petitions for administrative review by July 17, 1986.

ADDRESS: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305, Food and Drug

Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: S.K. Vadlamudi, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION: On December 26, 1979, Travenol-Genentech Diagnostics, Cambridge, MA 02139, submitted to CDRH an application for premarket approval of the GammaDab[®] [¹²⁵I] Alpha-Fetoprotein Radioimmunoassay Kit. The device is an alpha-fetoprotein (AFP) immunological test system indicated for use as an aid in the detection of fetal open neural tube defects. The device is an in vitro radioimmunoassay indicated for the quantitative measurement of alpha-fetoprotein (AFP) in maternal serum at 15 to 19 weeks gestation and in amniotic fluid at 15 to 20 weeks gestation. The device, when used in conjunction with ultrasonography or amniography, and amniotic fluid acetylcholinesterase testing, is safe and effective for use as an aid in the detection of fetal open neural tube defects. The application was reviewed on January 16, 1984, by the Immunology Devices Panel, an FDA advisory committee, which recommended approval of the application. On April 30, 1986, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at CDRH—contact S.K. Vadlamudi. (HFZ-440), address above.

Opportunity for Administrative Review

Section 551(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under Part 12 (21 CFR Part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory