

Purpose: This Panel is charged with conducting the initial review of grant applications on research that will provide (1) Severity and Acuity Measures for Illness and Injury for Children; (2) Child and Adolescent Patient Outcomes and Outcome Measures; (3) Cost of Emergency Medical Services for Children; and (4) Emergency Medical Services for Children (EMSC) System Organization, Configuration, and Operation.

Agenda: The open session of the meeting on July 20, from 8:30 a.m. to 9:30 a.m., will be devoted to a business meeting covering administrative matters. During the closed session, the committee will be reviewing and discussing grant applications dealing with health services research issues. In accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C., 552b(c)(6), it has been determined that this latter session will be closed because the discussions are likely to reveal personal information concerning individuals associated with the grant applications. This information is exempt from mandatory disclosure.

Anyone wishing to obtain a roster of members or other relevant information should contact Gerald E. Calderone, Ph.D., Agency for Health Care Policy and Research, Suite 400, 2101 East Jefferson Street, Rockville, Maryland 20852, Telephone (301) 595-2462.

Agenda items for this meeting are subject to change as priorities dictate.

Dated: June 21, 1995.

Clifton R. Gaus,

Administrator.

[FR Doc. 95-15926 Filed 6-28-95; 8:45 am]

BILLING CODE 4160-90-M

Food and Drug Administration

[Docket No. 95N-0185]

Drug Export; Arimidex (Anastrozole) 1 Milligram (mg) Tablet

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Zeneca Pharmaceuticals Inc., has filed an application requesting conditional approval for the export of the human drug Arimidex (Anastrozole) 1 mg tablet to the United Kingdom.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: James E. Hamilton, Center for Drug

Evaluation and Research (HFD-310), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301-594-3150.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Zeneca Pharmaceuticals, Inc., 1800 Concord Pike, P.O. Box 15437, Wilmington, DE 19850-5437, has filed an application requesting conditional approval for the export of the human drug Arimidex (Anastrozole) 1 mg tablet to the United Kingdom. This product is used for the treatment of advanced colorectal cancer. The application was received and filed in the Center for Drug Evaluation and Research on May 30, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by July 10, 1995, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: June 19, 1995.

Betty L. Jones,

Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 95-15969 Filed 6-28-95; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 95N-0184]

Drug Export; Tomudex® (Paltitrexid) 2 Milligrams (MG) Powder for Infusion and 5 Milliliters (ML) Clear Glass Vial

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Zeneca Pharmaceuticals, Inc., has filed an application requesting conditional approval for the export of the human drug Tomudex® (Paltitrexid) 2 mg powder for infusion and 5 mL clear glass vial to the United Kingdom.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: James E. Hamilton, Center for Drug Evaluation and Research (HFD-310), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301-594-3150.

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