Time and Date: 9 a.m.-5 p.m., February 13, 1998.

Place: Doubletree Hotel, 18740 Pacific Highway South, Seattle, Washington 98188, telephone 206/246–8600, fax 206/431–8687.

Status: Open to the public, limited only by the space available.

Purpose: This committee is charged with providing advice and guidance to the Director, CDC, regarding the scientific merit and direction of the Hanford Thyroid Morbidity Study. The Committee will review development of the study protocol and recommend changes of scientific merit to CDC, and advise on the conduct of a full-scale epidemiologic study using the approved protocol. During the conduct of the full-scale epidemiologic study, the Committee will advise CDC on the design and conduct of the study and analysis of the results.

Matters to be Discussed: The Committee will discuss the progress and updates on the status of various components of the Hanford Thyroid Disease Study being conducted by the Fred Hutchinson Cancer Research Center. Agenda items include: National Center for Environmental Health (NCEH) activities on the progress of current studies, an update on the Native American component, and public involvement activities.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Mike Donnelly, Public Health Advisor, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, (F–35), Atlanta, Georgia 30341–3724, telephone 770/488–7040, FAX 770/488–7044.

Dated: January 23, 1998.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–2437 Filed 1–29–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 84N–0102]

Cumulative List of Orphan Drug and Biological Designations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a cumulative list of designated orphan drugs and biologics as of December 31, 1997. FDA has announced the availability of previous lists, which are brought up-to-date monthly, identifying the drugs and biologicals granted orphan-drug designation under the Federal Food, Drug, and Cosmetic Act (the act).

ADDRESSES: Copies of the list of current orphan-drug designations and of any future lists are or will be available from the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and the Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3666.

FOR FURTHER INFORMATION CONTACT: Erica K. McNeilly, Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0983.

SUPPLEMENTARY INFORMATION: FDA's Office of Orphan Products Development (OPD) reviews and takes final action on applications submitted by sponsors seeking orphan-drug designation under section 526 of the act (21 U.S.C. 360bb). In accordance with this section of the act, which requires public notification of designations, FDA maintains a list of designated orphan drugs and biologicals. This list is made current on a monthly basis and is available upon request from OPD (contact identified above). At the end of each calendar year, the agency publishes an up-to-date cumulative list of designated orphan drugs and biologicals, including the names of designated compounds, the specific disease or condition for which the compounds are designated, and the sponsors' names and addresses. The cumulative list of compounds receiving orphan-drug designation through 1988 was published in the **Federal Register** of April 21, 1989 (54 FR 16294). This list is available on request from FDA's Dockets Management Branch (address above). Those requesting a copy should specify the docket number found in brackets in the heading of this notice.

The list that is the subject of this notice consists of designated orphan drugs and biologicals through December 31, 1997, and, therefore, brings the March 13, 1997 (62 FR 11900) publication up to date.

The orphan-drug designation of a drug or biological applies only to the sponsor who requested the designation. Each sponsor interested in developing an orphan drug or biological must apply for orphan-drug designation in order to obtain exclusive marketing rights. Any request for designation must be received by FDA before the submission of a marketing application for the proposed indication for which designation is requested. (See 53 FR 47577, November 23, 1988.) Copies of the regulations (see 57 FR 62076, December 29, 1992) for use in preparing an application for orphan-drug designation may be obtained from the OPD (address above).

The names used in the cumulative list for the drug and biological products that have not been approved or licensed for marketing may not be the established or proper names approved by FDA for these products if they are eventually approved or licensed for marketing. Because these products are investigational, some may not have been reviewed for purposes of assigning the most appropriate established proper name.

Dated: January 21, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–2265 Filed 1–29–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98M–0039]

NIC Ltd.; Premarket Approval of NiC1800 Needle Disposal System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application submitted by NIC Ltd., Half Moon Bay, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of NiC1800 Needle Disposal System. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 26, 1997, of the approval of the application.

DATES: Petitions for administrative review by March 2, 1998.

ADDRESSES: 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Chiu S. Lin, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913.

SUPPLEMENTARY INFORMATION: On August 8, 1997, NIC Ltd., Half Moon Bay, CA 94019, submitted to CDRH an application for premarket approval of the NiC1800 Needle Disposal System. The device is a needle destruction