cumulative list of orphan drug and biological designations. This list includes the name of the drug or biological, the specific disease/condition for which the drug or biological is designated, and information about the sponsor such as the name, address, telephone, and contact.

At the end of each calendar year, the agency publishes a cumulative list of orphan drug and biological designations current through the calendar year. The list that is the subject of this notice is the cumulative list of orphan drug and biological designations through December 31, 2000, and, therefore, brings the March 1, 2000 (65 FR 11066) publication up to date. This list is available upon request from the Dockets Management Branch (address above). Those requesting a copy should specify Docket No. 84N–0102, which is the docket number for this notice. In addition, the list is updated monthly and is available upon request from OPD or the FDA's Dockets Management Branch (address above). The current list is also available on the Internet at http://www.fda.gov/orphan.

The orphan designation of a drug or biological applies only to the sponsor who requested the designation. Each sponsor interested in developing a drug or biological for an orphan indication must apply for orphan 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 (21 CFR 316.23). Copies of the orphan drug regulations (21 CFR part 316) (57 FR 62076, December 29, 1992) and explanatory background materials for use in preparing an application for orphan designation may be obtained from OPD (address above).

The names of the drugs and biologicals shown in the cumulative list of orphan designations may change upon marketing approval/licensing, reflecting the established, proper name approved by FDA. Because drugs and biologicals not approved/licensed for marketing are investigational, the appropriate established, proper name has not necessarily been assigned.

Dated: March 27, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–8061 Filed 4–2–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Consumer Briefing on Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathies (TSE)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following consumer meeting: Consumer Briefing on Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathies (TSE). This briefing is the first in a series of consumer briefings on the consumer protection priorities discussed by the agency and consumers at the December 13, 2000, Consumer Roundtable on Consumer Protection Priorities meeting. These consumer briefings enable the agency and consumers to sustain a dialogue on FDA priorities of high consumer interest in the spirit of openness, transparency, and participation. This consumer briefing will provide an update on FDA's efforts to ensure the safety of products that may contain or are manufactured with bovine-derived ingredients.

Date and Time: The briefing will be held on April 16, 2001, 1 p.m. to 4:30 p.m. Registration will open at 12 noon.

Location: The briefing will be held at Holiday Inn Capitol, Columbia II, 550 C St., SW., Washington, DC.

Contact: Karen R. Mahoney, Office of Consumer Affairs (HFE–88), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4393, FAX 301–827–2866, e-mail: Kmahoney@oc.fda.gov.

Registration: Preregistration is required as space is very limited. Send registration information (including name, title, organization/firm name, address, telephone, fax number and e-mail) to the contact person by April 13, 2001. Preregistered consumer attendees will be given first priority for seating.

If you need any special accommodations due to disability, please contact Karen R. Mahoney (address above) by April 13, 2001.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents a page.

SUPPLEMENTARY INFORMATION: The consumer briefing is an opportunity for the agency to meet with consumers and to discuss issues and concerns as well as how FDA and consumers can work together to keep consumers informed and involved.

Procedure: The briefing is open to the public. There will be an open public session at the conclusion of the briefing where interested persons can respond to the topics and issues discussed during the briefing.

Dated: March 27, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–8062 Filed 4–2–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK): Opportunity for Cooperative Research and Development Agreements (CRADAs) To Identify Novel Candidate Genes for Obesity and Insulin Resistance Using Global Gene Expression Profiling

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) announces the opportunity for Cooperative Research and Development Agreements (CRADAs) to identify novel candidate genes for obesity and insulin resistance using global gene expression profiling. The NIH seeks potential Collaborator(s) wishing to provide expertise in (1) identification of genes that may contribute to the development of obesity; (2) identification of genes that may contribute to the development of insulin resistance; (3) characterization of potentially novel sub-pathways of insulin signaling mechanisms; and (4) identification of genes regulated by free-fatty acid.

The NIDDK seeks capability statements from parties interested in entering into a potential CRADA to identify novel candidate genes for obesity and insulin resistance using global gene expression profiling. Collaborator applicants developing capability statements may also include proposals to provide funding for possible commercial uses of interest to the Collaborator. The availability of private sector support may increase the feasibility of particular aspects of the