Time and Date: 8:30 a.m.–4 p.m., December 10, 1998.

Place: Salt Lake City Hilton, 150 West 500 South, Salt Lake City, Utah 84101, telephone 801–532–3344, fax 801–531–0705.

Status: Open to the public, limited only by the space available. The meeting room will accommodate approximately 75 people.

Purpose: This subcommittee reviews and provides consensus advice to CDC and ATSDR on their public health activities and research at the Fernald, Ohio, site.

Matters to be Discussed: Agenda items include an update on worker studies related to the Fernald site from NIOSH; an update on risk assessment from NCEH; selection of FHES representative for an evaluation project; and subcommittee discussion.

Name: Inter-tribal Council on Hanford Health Projects (ICHHP) in Association with the Hanford Health Effects Subcommittee (HHES).

Time and Date: 8 a.m.–12 noon, December 10, 1998.

Place: Salt Lake City Hilton, 150 West 500 South, Salt Lake City, Utah 84101, telephone 801–532–3344, fax 801–531–0705.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people.

Purpose: The purpose of this meeting is to address issues that are unique to tribal involvement with the HHES, including considerations regarding a proposed medical monitoring program and discussion of cooperative agreement activities designed to provide support for capacity-building activities in tribal environmental health expertise and for tribal involvement in HHES.

Matters to be Discussed: Agenda items will include a dialogue on issues that are unique to tribal involvement with the HHES. This will include exploring cooperative agreement activities in environmental health capacity building and providing support for tribal involvement in and representation on the HHES.

Name: Hanford Health Effects Subcommittee (HHES).

Times and Dates: 1 p.m.–5 p.m., December 10, 1998; 8:30 a.m.–3:30 p.m., December 11, 1998.

Place: Salt Lake City Hilton, 150 West 500 South, Salt Lake City, Utah 84101, telephone 801–532–3344, fax 801–531–0705.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people.

Purpose: This subcommittee reviews and provides consensus advice to CDC and ATSDR on their public health activities and research at the Hanford Nuclear Reservation.

Matters to be Discussed: Agenda items will include an update from the ICHHP; the review and approval of Minutes of the previous meeting; updates from ATSDR, NCEH, and NIOSH; reports from the Outreach, Public Health Assessment, Public Health Activities, and Studies Workgroups; and other issues and topics as necessary.

Name: Idaho National Engineering and Environmental Laboratory Health Effects Subcommittee (INEELHES).

Time and Date: 8:30 a.m.–5:30 p.m., December 10, 1998.

Place: Salt Lake City Hilton, 150 West 500 South, Salt Lake City, Utah 84101, telephone 801–532–3344, fax 801–531–0705.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people.

Purpose: This subcommittee reviews and provides consensus advice to CDC and ATSDR on their public health activities and research at the INEEL.

Matters to be Discussed: Agenda items include an update on the status of research at the INEEL, discussion on document management at DOE; and subcommittee discussions.

Name: Savannah River Site Health Effects Subcommittee (SRSHES).

Time and Date: 8:30 a.m.–5:30 p.m., December 10, 1998.

Place: Salt Lake City Hilton, 150 West 500 South, Salt Lake City, Utah 84101, telephone 801–532–3344, fax 801–531–0705.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people.

Purpose: This subcommittee reviews and provides consensus advice to CDC and ATSDR on their public health activities and research at the SRS.

Matters to be Discussed: Agenda items include an update from ATSDR on its research; the schedule for release to the public of the Phase II report; presentations by NCEH, ATSDR, and NIOSH on the design of their respective web pages; and subcommittee discussion.

All agenda items are subject to change as priorities dictate.

FOR FURTHER INFORMATION CONTACT: Information on the HHES and the ICHHP may be obtained from Leslie C. Campbell, Executive Secretary, HHES, or Marilyn Palmer, Committee Management Specialist, Division of Health Assessment and Consultation, ATSDR, 1600 Clifton Road, NE (E–56), Atlanta, GA 30333, telephone 1–800–447–1544, fax 404–639–6075. Information on the FHES may be obtained from Steven A. Adams, Executive Secretary, FHES, Radiation Studies Branch (RSB), Division of Environmental Hazards and Health Effects (DEHHE), NCEH, CDC, 4770 Buford Highway, NE, (F–35), Atlanta, Georgia 30341–3724, telephone 770–488–7040, fax 770–488–7044. Information on the INEELHES may be obtained from Arthur J. Robinson, Jr., Executive Secretary, INEELHES, RSB, DEHHE, NCEH, CDC, 4770 Buford Highway, NE, (F–35), Atlanta, Georgia 30341–3724, telephone 770–488–7040, fax 770–488–7044. Information on the SRSHES may be obtained from Paul G. Renard, Executive Secretary, SRSHES, RSB, DEHHE, NCEH, CDC, 4770 Buford Highway, NE, (F–35), Atlanta, Georgia 30341–3724, telephone 770–488–7040, fax 770–488–7044.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and ATSDR.

Dated: November 13, 1998.

Carolyn J. Russell,

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

[FR Doc. 98–30913 Filed 11–18–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–1000]

Danbury Pharmacal, Inc.; Withdrawal of Approval of 61 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 61 abbreviated new drug applications (ANDA's). Danbury Pharmacal, Inc., notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

EFFECTIVE DATE: December 21, 1998.

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, Center for Drug

Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: Danbury Pharmacal, Inc., 131 West St., Danbury, CT 16810, has informed FDA that the drug products listed in the following table are no longer marketed and has requested that FDA withdraw approval of the applications. Danbury Pharmacal, Inc., has also, by its request, waived its opportunity for a hearing.

ANDA No.	Drug
63–082	Clindamycin Hydrochloride Capsules USP, 75 milligrams (mg)
71–098	Propranolol Hydrochloride Tablets USP, 60 mg
71–183	Propranolol Hydrochloride Tablets USP, 90 mg
71–494	Oxazepam Tablets USP, 15 mg
71–498	Propranolol Hydrochloride and Hydrochlorothiazide Tablets USP, 40 mg/25 mg
71–501	Propranolol Hydrochloride and Hydrochlorothiazide Tablets USP, 80 mg/25 mg
71–905	Ibuprofen Tablets USP, 200 mg
72–113	Haloperidol Tablets USP, 10 mg
72–134	Perphenazine and Amitriptyline Hydrochloride Tablets USP, 4 mg/25 mg
72–135	Perphenazine and Amitriptyline Hydrochloride Tablets USP, 4 mg/50 mg
72–353	Haloperidol Tablets USP, 20 mg
72–539	Perphenazine and Amitriptyline Hydrochloride Tablets USP, 2 mg/10 mg
72–540	Perphenazine and Amitriptyline Hydrochloride Tablets USP, 4 mg/10 mg
72–541	Perphenazine and Amitriptyline Hydrochloride Tablets USP, 2 mg/25 mg
72–981	Fenoprofen Calcium Capsules USP
72–982	Fenoprofen Calcium Capsules USP
72–996	Indomethacin Capsules USP, 25 mg
72–997	Indomethacin Capsules USP, 50 mg
80–393	Reserpine Tablets USP, 0.25 mg
80–522	Isoniazid Tablets USP, 50 mg
80–523	Isoniazid Tablets USP, 100 mg
80–679	Reserpine Tablets USP, 0.1 mg
80–696	Chlorpheniramine Maleate Tablets USP, 4 mg
80–749	Reserpine Tablets USP, 1 mg
80–905	Phenytoin Sodium Capsules USP, 100 mg
80–907	Rauwolfia Serpentina Tablets USP, 50 mg
80–908	Propoxyphene Hydrochloride Capsules USP, 65 mg
80–914	Rauwolfia Serpentina Tablets USP, 100 mg
83–029	Propantheline Bromide Tablets USP, 15 mg
83–123	Brompheniramine Maleate Tablets USP, 4 mg
83–305	Niacin Tablets USP, 500 mg
83–712	Promethazine Hydrochloride Tablets USP, 12.5 mg
83–847	Trichlormathiazide Tablets USP, 2 mg
83–855	Trichlormethiazide Tablets USP, 4 mg
84–274	Meprobamate Tablets USP, 600 mg
84–347	Dicyclomine Hydrochloride Capsules USP, 10 mg
84–362	Glutethimide Tablets USP, 500 mg
84–*402	Bethanechol Chloride Tablets USP, 5 mg
84–602	Dicyclomine Hydrochloride Tablets USP, 20 mg
85–094	Triprolidine Hydrochloride Tablets USP, 2.5 mg
85–584	Quinidine Sulfate Tablets USP, 100 mg
86–086	Pentaerythritol Tetranitrate Tablets USP, 20 mg
86–580	Cyproheptadine Hydrochloride Tablets USP, 4 mg
86–900	Glycopyrrolate Tablets USP, 2 mg
86–901	Chlorzoxazone Tablets USP, 250 mg
86–902	Glycopyrrolate Tablets USP, 1 mg
87–419	Dipyridamole Tablets USP, 25 mg
87–432	Dipyridamole Tablets USP, 75 mg
87–550	Butalbital and Acetaminophen, 50 mg/325 mg
87–667	Sulfinpyrazone Tablets USP, 100 mg
87–767	Hydroxyzine Pamoate Capsules USP (equivalent to 50 mg Hydroxyzine Hydrochloride)
87–790	Hydroxyzine Pamoate Capsules USP (equivalent to 100 mg Hydroxyzine Hydrochloride)
87–874	Carisoprodol Compound Tablets
88–620	Amitriptyline Hydrochloride Tablets USP, 10 mg
88–621	Amitriptyline Hydrochloride Tablets USP, 25 mg
88–622	Amitriptyline Hydrochloride Tablets USP, 50 mg
88–633	Amitriptyline Hydrochloride Tablets USP, 75 mg
88–634	Amitriptyline Hydrochloride Tablets USP, 100 mg
88–635	Amitriptyline Hydrochloride Tablets USP, 150 mg
88–755	Thioridazine Hydrochloride Tablets USP, 25 mg
88–800	Dipyridamole Tablets USP, 50 mg

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective December 21, 1998.

Dated: November 4, 1998.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 98–30878 Filed 11–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0781]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Avapro® 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Avapro® (irbesartan). Avapro® is indicated for the treatment of hypertension. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Avapro® (U.S. Patent No. 5,270,317) from Sanofi, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 7, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Avapro® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Avapro® is 1,616 days. Of this time, 1,246 days occurred during the testing phase of the regulatory review period, while 370 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: April 30, 1993. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 30, 1993.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: September 26, 1996. FDA has verified the applicant's claim that the new drug application (NDA) for Avapro® (NDA 20–757) was initially submitted on September 26, 1996.

3. *The date the application was approved*: September 30, 1997. FDA has verified the applicant's claim that NDA 20–757 was approved on September 30, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 194 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before January 19, 1999, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before May 18, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 4, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–30990 Filed 11–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICE

Food and Drug Administration

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.