specifications/statements of work and grants announcements; (4) participates with top program management in program planning, policy determination, evaluation, and directions concerning acquisition and grants strategies and execution; (5) provides innovative program-solving methods in the coordination of international procurement and grants for a wide range plan with partners in virtually all major domestic and international health agencies dealing with the United Nations Foundation health priorities/issues, to include resolution of matters with the Department of State; (6) executes contracts and grants in support of international activities; (7) provides business management oversight for contracts and assistance awards; (8) participates with top program management in program planning, policy determination, evaluation, and directions concerning acquisition and assistance strategies and execution; (9) maintains branch's official contract and assistance files; (10) maintains a close working relationship with CDC program office components in carrying out their missions; (11) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with the overall objectives of PGO.

Acquisition and Assistance Branch VIII (CAJHV). This branch supports the CDC Office of the Director acquisition requirements by performing the following: (1) Plans, directs, and conducts the acquisition of non-personal services, supplies, equipment, research and development, studies, and data collection for CDC through a variety of contractual mechanisms (competitive and non-competitive); (2) reviews statements of work from a management point of view for conformity to laws, regulations, and policies, and negotiates and issues contracts; (3) provides continuing surveillance of financial and administrative aspects of acquisition-supported activities to assure compliance with appropriate DHHS and CDC policies; (4) gives technical assistance, where indicated, to improve the management of acquisition activities, and responds to requests for management information from the Office of the Director, headquarters, regional staffs, CDC program offices and the public; (5) performs contract and purchasing administrative activities including coordination and negotiation of contract modifications, reviewing and approving contractor billings, resolving audit findings, and performing close-out/termination activities; (6) provides for the collection and reporting of business management and programmatic data, and analyzes and monitors business management data on grants and cooperative agreements; (7) assures that contractor performance is in accordance with contractual commitments; (8) provides leadership and guidance to CDC project officers and program officials; (9) provides leadership, direction, procurement options, and approaches in developing specifications/statements of work and contract awards; (10) participates with top program management in program planning, policy determination, evaluation, and directions concerning acquisition strategies and execution; (11) maintains branch's official contract files; (12) maintains a close working relationship with CDC program office components in carrying out their missions; (13) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with the overall objectives of PGO.

Dated: August 10, 2005.

William H. Gimson,

Chief Operating Officer, Centers for Disease Control and Prevention (CDC).

[FR Doc. 05–17073 Filed 8–26–05; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0331]

Able Laboratories, Inc.; Withdrawal of Approval of Ten Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of ten abbreviated new drug applications (ANDAs) held by Able Laboratories, Inc. (Able Labs), One Able Dr., Cranbury, NJ 08512. Able Labs has initiated a class II recall of the products covered by these ANDAs. The company has requested that the applications be withdrawn and has waived its opportunity for a hearing.

DATES: Effective August 29, 2005.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: On May 25, 2005, Able Labs notified the agency that, because of improper laboratory practices and noncompliance with standard operating procedures, Able Labs was initiating a voluntary, class II recall of the products covered by the ANDAs listed in the table of this document. The company voluntarily requested withdrawal of approval of the ANDAs under § 314.150(d) (21 CFR 314.150(d)), and waived its opportunity for a hearing, provided under § 314.150(a) and (b). The following ANDAs are affected by this action:

ANDA No.	Drug
40–395	Diphenoxylate Hydrochloride (HCl) and Atropine Sulfate Tablets USP, 2.5 milligrams (mg)/0.025 mg
40–404	Methylphenidate HCl Tablets USP, 5 mg, 10 mg, and 20 mg
40–407	Prochlorperazine Suppositories USP, 2.5 mg, 5 mg, and 25 mg
40–452	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg
40–459	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/60 mg
71–780	Clorazepate Dipotassium Tablets USP, 3.75 mg
71–781	Clorazepate Dipotassium Tablets USP, 7.5 mg
71–782	Clorazepate Dipotassium Tablets USP, 15 mg

ANDA No.	Drug
75–838	Propoxyphene Napsylate and Acetaminophen Tablets USP, 100 mg/650 mg
76–032	Methylphenidate HCl Exended-Release Tablets USP, 20 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 5.105(a)), approval of the ANDAs listed in the table of this document, and all amendments and supplements thereto, is withdrawn, effective August 29, 2005. Thereafter, distribution of the products in interstate commerce without approved applications is illegal and subject to regulatory action. Also, on the basis of the circumstances described in this document that led to the recall of the products and their subsequent removal from the market, the agency will remove the products from the agency's list of drug products with effective approvals, published under the title ''Approved Drug Products With Therapeutic Equivalence Evaluations.'' This document serves as notice of the removal of the products covered by the ANDAs listed in this document from the list of approved drug products. Distribution of these products in interstate commerce without approved applications is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the act (21 U.S.C. 355(a) and 331(d)).

Dated: August 15, 2005.

Steven Galson,

Director, Center for Drug Evaluation and Research.

[FR Doc. 05–17151 Filed 8–26–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Research Review Subcommittee of the Cellular, Tissue and Gene Therapies Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a subcommittee of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Subcommittee: Research Review Subcommittee of the Cellular, Tissue and Gene Therapies Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 29, 2005, from 8 a.m. to 4 p.m.

Location: Holiday Inn Select, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Gail Dapolito or Sheila Langford, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512389. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 29, 2005, the subcommittee will listen to presentations about the research program at the Office of Cellular, Tissue and Gene Therapies (OCTGT), Center for Biologics Evaluation and Research (CBER). The program is intended to provide dynamic, responsive, cutting edge research to contribute to OCTGT's regulatory mission and facilitate development of safe and effective biological products. The subcommittee will discuss the program and make recommendations to the Cellular Tissue and Gene Therapies Advisory Committee at a future open meeting of the full Committee. Information regarding CBER's scientific program is outlined in its Strategic Plan of 2004 and is available to the public on the Internet at: *http://www.fda.gov/cber/inside/mission.htm*. Information regarding FDA's Critical Path to New Medical Products is available to the public on the Internet at: *http://www.fda.gov/oc/initiatives/criticalpath/*.

Procedure: On September 29, 2005, from 8 a.m. to approximately 1:20 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by September 22, 2005. Oral presentations from the public will be scheduled between approximately 11:20 a.m. and 12:20 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by September 22, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Subcommittee Deliberations: On September 29, 2005, from approximately 1:20 p.m. to 4 p.m. the meeting will be closed to the public. The meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)) and to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). The subcommittee will discuss internal research programs in OCTGT, CBER.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Gail Dapolito at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 18, 2005.

Scott Gottlieb,

Deputy Commissioner for Policy.

[FR Doc. 05–17149 Filed 8–26–05; 8:45 am]

BILLING CODE 4160–01–S