

which achieves positive public health outcomes; (5) plans and coordinates marketing efforts to achieve CDC's health impact goals related to people, places, and preparedness; (6) plans, directs, and coordinates information systems to support performance measurement and knowledge management related to CDC's health impact goals and other data systems to measure progress towards accomplishment of the goals; (7) assures that health information, interventions, and programs are appropriately packaged and released in a timely manner; (8) collects, analyzes and disseminates national health statistics on vital events and health activities; (9) applies the latest public health informatics strategies and information technology to public health practice, research, and learning; (10) provides consultation and technical assistance, public health surveillance and informatics, health information systems, prevention effectiveness, scientific communications, behavioral science, statistics, and development of community health practice guidance; (11) identifies critical cross-CDC relationships and devotes concerted, consistent and high-level attention to these relationships in order to maximize CDC's success in achieving priority health goals; and (12) provides leadership in the development and coordination of high-priority partnerships and sets strategy and goals for working with the health sectors and partners (business and workers, health care, education, federal agencies, foundations, faith and community organizations, and public health community including state and local health organizations).

*Office of the Director (CPA).* (1) Provides leadership and guidance and evaluates the activities of the CCHIS; (2) develops overarching goals and objectives and provides leadership, policy formation, scientific oversight and guidance in program planning and development; (3) coordinates assistance provided by CCHIS to other CDC components, other federal, state, and local agencies, the private sector and other nations; (4) provides and coordinates resource management requirements for CCHIS; (5) develops and provides guidance on workforce development activities within CCHIS and coordinates the recruitment, assignment, technical supervision and career development of staff, with emphasis on goals for equal employment opportunity and diversity where appropriate; (6) develops strategies, programs and procedures to

ensure quality and integrity in the research activities; and (7) collaborates as appropriate with other coordinating centers, centers, offices, institutes of CDC, and other public health service agencies and other federal agencies.

Dated: August 10, 2005.

**William H. Gimson,**

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

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**BILLING CODE 4160-18-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 70 FR 46527-30, dated August 10, 2005) is amended to reflect the reorganization of the Procurement and Grants Office, within the Office of the Chief Operating Officer.

Section C-B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the title and functional statement for the *Procurement and Grants Office (CAJ7), Office of the Chief Operating Officer (CAJ)*, and insert the following:

*Procurement and Grants Office (CAJH).* (1) Advises the Director, Centers for Disease Control and Prevention (CDC), the Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), and their staff, and provides leadership and direction for CDC acquisition, assistance, and materiel management activities; (2) plans and develops CDC-wide policies, procedures, and practices in acquisition, assistance, and materiel management areas; (3) obtains research and development, services, equipment, supplies, and construction through acquisition processes; (4) maintains functions relating to personal property, transportation, and warehousing operations; (5) awards, administers, and terminates contracts, purchase orders, grants, and cooperative agreements; (6) maintains a continuing program of reviews, evaluations, inquiries, and oversight activities of CDC-wide acquisitions, assistance, and materiel

management operations to ensure adherence to laws, policies, procedures, and regulations; (7) maintains liaison with the Department of Health and Human Services (DHHS), General Services Administration (GSA), General Accounting Office (GAO), and other federal agencies on acquisition, assistance, and materiel management policies, procedures, and operating matters.

*Office of the Director (CAJH1).* (1) Provides overall leadership, guidance and coordination in all areas of the Procurement and Grants Office (PGO) activities; (2) develops and implements organizational strategic planning goals and objectives; (3) provides overall budgetary and human resource management, and administrative support; (4) directs and coordinates activities in support of the Department's Equal Employment Opportunity Program and employee development; (5) conducts continuing studies and analysis of branch activities; (6) provides technical and managerial direction for the development, implementation, and maintenance of the Integrated Contracts Expert System on a CDC-wide basis; (7) operates CDC's Small and Disadvantaged Business Program, and provides direction and support to various other socioeconomic programs encompassing acquisition and assistance activities; (8) develops technical requirements for support business practices through technology.

*Materiel Management Activity (CAJH12).* (1) Implements CDC-wide policies, procedures, and criteria required to implement federal and departmental regulations governing materiel management and transportation management; (2) evaluates operations to determine procedural changes needed to maintain effective management; (3) provides technical assistance to other parts of CDC on matters pertaining to materiel management, transportation management, fleet management, and agent cashier services; (4) develops, designs, and tests materiel management systems and procedures; (5) represents CDC on inter- and intra-departmental materiel and transportation management committees; (6) maintains liaison with the department and other federal agencies on materiel management, and transportation and traffic management matters; (7) establishes activity goals, objectives, and priorities, and assures their consistency and coordination with the overall objectives of PGO.

*Office of Policy, Oversight and Evaluation (CAJHK).* (1) Provides technical and managerial direction for the development of CDC-wide policies, procedures, and practices in the

acquisitions, assistance, and materiel management areas; (2) participates with senior management in program planning, policy determinations, evaluations, and decisions concerning acquisition, assistance, and materiel management; (3) provides direction for award, administration, measures of effectiveness and termination of contracts, purchase orders, grants, and cooperative agreements; (4) maintains a continuing program of reviews, evaluations, inquiries, and oversight activities of CDC-wide acquisitions, assistance, and materiel management operations to ensure adherence to laws, policies, procedures, and regulations; (5) maintains liaison with DHHS, GSA, GAO, and other Federal agencies on acquisition, assistance, and materiel management policy, procedures, and operating matters; (6) serves as central CDC receipt and referral point for all applications for assistance funds, including interfacing with the automated grants systems and relevant DHHS line of business agencies and distributing draft program announcements for review; (7) provides cost advisory support to acquisition and assistance activities with responsibility for initiating requests for audits and evaluations, and providing recommendations to contracting officer or grants management officer, as required; participates in negotiations with potential contractors and grantees, develops overhead rates for profit and nonprofit organizations, and provides professional advice on accounting and cost principles in resolving audit exceptions as they relate to the acquisition and assistance processes.

*Buildings and Facilities Contracts Branch (CAJHL).* (1) Directs and controls acquisition planning activities to assure total program needs are addressed and procurements are conducted in a logical, appropriate, and timely sequence; (2) plans, directs, and conducts the acquisition of non-personal services, institutional support services, architect-engineering services, construction of new buildings, alterations, renovations, commodities, and equipment in support of CDC/ATSDR facilities, utilizing a wide variety of contract types and pricing arrangements; (3) provides leadership, direction, procurement options, and approaches in developing specification/statements of work and contract awards; (4) 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; (5) performs simplified acquisition activities in support of CDC/ATSDR program offices; (6) assures that contractor performance is in accordance with contractual commitments; (7) provides leadership and guidance to CDC/ATSDR project officers and program officials; (8) participates with senior program management in program planning, policy determination, evaluation, and directions concerning acquisition strategies and execution; (9) plans, directs, and coordinates activities of the branch; (10) maintains branch's official contracts files; (11) maintains a close working relationship with facilities management and other CDC components in carrying out their missions; (12) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with overall objectives of PGO.

*Acquisition and Assistance Branch I (CAJHM).* This branch supports the Coordinating Center for Infectious Diseases and the National Center for HIV, STD, and TB Prevention 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) plans, directs and conducts assistance management activities for CDC through the awards for grants and cooperative agreements (competitive and non-competitive); (3) reviews statements of work and assistance applications from a management point of view for conformity to laws, regulations, and policies, and negotiates and issues contract, grant, and cooperative agreement awards; (4) provides continuing surveillance of financial and administrative aspects of acquisition and assistance-supported activities to assure compliance with appropriate DHHS and CDC policies; (5) gives technical assistance, where indicated, to improve the management of acquisition and assistance-supported activities, and responds to requests for management information from the Office of the Director, headquarters, regional staffs, CDC offices and the public; (6) performs contract and purchasing administrative activities including coordinating and negotiation of contract modifications, reviewing and approving contractor billings, resolving audit findings, and performing close-out/termination activities; (7) provides for the collection and reporting of business management and programmatic data, and analyzes

and monitors business management data on grants and cooperative agreements; (8) assures that contractor and grantee performance is in accordance with contractual and assistance commitments; (9) provides leadership and guidance to CDC projects officers and program officials; (10) provides leadership, direction, procurement options, and approaches in developing specifications/statements of work and contract awards; (11) plans, directs, coordinates, and conducts the grants management functions and processes in support of assistance awards, including cooperative agreements, discretionary grants, block grants, and formula grants, to state and local governments, universities, colleges, research institutions, hospitals, public and private organizations, small businesses, and minority- and/or women-owned businesses for CDC; (12) participates with top program management in program planning, policy determination, evaluation, and directions concerning acquisition and assistance strategies and execution; (13) maintains branch's official contract and assistance files; (14) maintains a close working relationship with CDC program office components in carrying out their missions; (15) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with the overall objectives of PGO.

*Acquisition and Assistance Branch II (CAJHN).* This branch supports the Coordinating Center for Infectious Diseases, the National Center for Infectious Diseases, the National Immunization Program, and CDC Office of the Director assistance 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) plans, directs, and conducts assistance management activities for CDC through the awards of grants and cooperative agreements (competitive and non-competitive); (3) reviews statements of work and assistance applications from a management point of view for conformity to laws, regulations, and policies, and negotiates and issues contract, grant, and cooperative agreement awards; (4) provides continuing surveillance of financial and administrative aspects of acquisition and assistance-supported activities to assure compliance with appropriate DHHS and CDC policies; (5) gives technical assistance, where indicated, to

improve the management of acquisition and assistance-supported activities, and responds to requests for management information from the Office of the Director, headquarters, regional staffs, CDC program offices and the public; (6) 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; (7) provides for collection and reporting of business management and programmatic data, and analyzes and monitors business management data on grants and cooperative agreements; (8) assures that contractor and grantee performance is in accordance with contractual and assistance commitments; (9) provides leadership and guidance to CDC project officers and program officials; (10) provides leadership, direction, procurement options, and approaches in developing specifications/statements of work and contract awards; (11) plans, directs, coordinates, and conducts the grants management functions and processes in support of assistance awards, including cooperative agreements, discretionary grants, block grants, and formula grants, to state and local governments, universities, colleges, research institutions, hospitals, public and private organizations, small businesses, and minority- and/or women-owned businesses for CDC; (12) participates with top program management in program planning, policy determination, evaluation, and directions concerning acquisition and assistance strategies and execution; (13) maintains branch's official contract and assistance files; (14) maintains a close working relationship with CDC program office components in carrying out their missions; (15) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with the overall objectives of PGO.

*Acquisition and Assistance Branch III (CAJHP).* This branch supports the Coordinating Center for Health Promotion, the National Center for Birth Defects and Developmental Disabilities, the National Center for Chronic Disease Prevention and Health Promotion, and the Office of Genomics and Disease Prevention 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) plans, directs, and conducts assistance management

activities for CDC through the awards of grants and cooperative agreements (competitive and non-competitive); (3) reviews statements of work and assistance applications from a management point of view for conformity to laws, regulations, and policies, and negotiates and issues contract, grant, and cooperative agreement awards; (4) provides continuing surveillance of financial and administrative aspects of acquisition and assistance-supported activities to assure compliance with appropriate DHHS and CDC policies; (5) gives technical assistance, where indicated, to improve the management of acquisition and assistance-supported activities, and responds to requests for management information from the Office of the Director, headquarters, regional staffs, CDC program offices and the public; (6) 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; (7) provides for the collection and reporting of business management and programmatic data, and analyzes and monitors business management data on grants and cooperative agreements; (8) assures that contractor and grantee performance is in accordance with contractual and assistance commitments; (9) provides leadership and guidance to CDC project officers and program officials; (10) provides leadership, direction, procurement options, and approaches in developing specifications/statements of work and contract awards; (11) plans, directs, coordinates, and conducts the grants management functions and processes in support of assistance awards, including cooperative agreements, discretionary grants, block grants, and formula grants, to state and local governments, universities, colleges, research institutions, hospitals, public and private organizations, small businesses, and minority- and/or women-owned businesses for CDC; (12) participates with top program management in program planning, policy determination, evaluation, and directions concerning acquisition and assistance strategies and execution; (13) maintains branch's official contract and assistance files; (14) maintains a close working relationship with CDC program office components in carrying out their missions; (15) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with the overall objectives of PGO.

*Acquisition and Assistance Branch IV (CAJHR).* This branch supports the Coordinating Center for Environmental Health and Injury Prevention, the National Center for Environmental Health, ATSDR, and the National Center for Injury Prevention and Control 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) plans, directs, and conducts assistance management activities for CDC through the awards of grants and cooperative agreements (competitive and non-competitive); (3) reviews statements of work and assistance applications from a management point of view for conformity to laws, regulations, and policies, and negotiates and issues contract, grant, and cooperative agreement awards; (4) provides continuing surveillance of financial and administrative aspects of acquisition and assistance-supported activities to assure compliance with appropriate DHHS and CDC policies; (5) gives technical assistance, where indicated, to improve the management of acquisition and assistance-supported activities, and responds to requests for management information from the Office of the Director, headquarters, regional staffs, CDC program offices and the public; (6) performs contract and purchasing administrative activities including coordination and negotiation of contract modifications, reviewing and approving contractor billings, resolving audit findings, and performing closeout/termination activities; (7) provides for the collection and reporting of business management and programmatic data, and analyzes and monitors business management data on grants and cooperative agreements; (8) assures that contractor and grantee performance is in accordance with contractual and assistance commitments; (9) provides leadership and guidance to CDC project officers and program officials; (10) provides leadership, direction, procurement options, and approaches in developing specifications/statements of work and contract awards; (11) plans, directs, coordinates, and conducts the grants management functions and processes in support of assistance awards, including cooperative agreements, discretionary grants, block grants, and formula grants, to state and local governments, universities, colleges, research institutions, hospitals, public and private organizations, small

businesses, and minority- and/or women-owned businesses for CDC; (12) participates with top program management in program planning, policy determination, evaluation, and directions concerning acquisition and assistance strategies and execution; (13) maintains branch's official contract and assistance files; (14) maintains a close working relationship with CDC program office components in carrying out their missions; (15) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with the overall objectives of PGO.

*Acquisition and Assistance Branch V (Field)(CAJHS).* This branch supports the National Institute for Occupational Safety and Health (NIOSH) 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) plans, directs, and conducts assistance management activities for CDC through the awards of through grants and cooperative agreements (competitive and non-competitive); (3) reviews statements of work and assistance applications from a management point of view for conformity to laws, regulations, and policies, and negotiates and issues contract, grant, and cooperative agreement awards; (4) provides continuing surveillance of financial and administrative aspects of acquisition and assistance-supported activities to assure compliance with appropriate DHHS and CDC policies; (5) gives technical assistance, where indicated, to improve the management of acquisition and assistance-supported activities and responds to requests for management information from the Office of the Director, headquarters, regional staffs, and the public; (6) 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; (7) provides for the collection and reporting of business management and programmatic data, and analyzes and monitors business management data on grants and cooperative agreements; (8) assures that contractor and grantee performance is in accordance with contractual and assistance commitments; (9) provides leadership and guidance to CDC project officers and program officials; (10) provides leadership, direction, procurement

options, and approaches in developing specification/statements of work and contract awards; (11) plans, directs, coordinates, and conducts the grants management functions and processes in support of assistance awards, including cooperative agreements, discretionary grants, block grants, and formula grants, to state and local governments, universities, colleges, research institutions, hospitals, public and private organizations, small businesses, and minority- and/or women-owned businesses for CDC; (12) participates with top program management in program planning, policy determination, evaluation, and directions concerning acquisition and assistance strategies and execution; (13) maintains branch's official contract and assistance files; (14) maintains a close working relationship with CDC components in carrying out their missions; (15) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with the overall objectives of PGO; (16) acquisition and assistance functions in support of NIOSH are accomplished with field office locations located in Pittsburgh, PA; Morgantown, WV; Cincinnati, OH; and Spokane, WA.

*Acquisition and Assistance Branch VI (CAJHT).* This branch supports the Coordinating Center for Health Information and Service, the National Center for Health Marketing, the National Center for Health Statistics, the National Center for Public Health Informatics, and the Coordinating Office of Terrorism Preparedness and Emergency Response 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) plans, directs, and conducts assistance management activities for CDC through the awards of grants and cooperative agreements (competitive and non-competitive); (3) reviews statements of work and assistance applications from a management point of view for conformity to laws, regulations, and policies, and negotiates and issues contract, grant, and cooperative agreement awards; (4) provides continuing surveillance of financial and administrative aspects of acquisition and assistance-supported activities to assure compliance with appropriate DHHS and CDC policies; (5) gives technical assistance, where indicated, to improve the management of acquisition and assistance-supported activities, and

responds to requests for management information from the Office of the Director headquarters, regional staffs, CDC program offices and the public; (6) 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; (7) provides for the collection and reporting of business management and programmatic data, and analyzes and monitors business management data on grants and cooperative agreements; (8) assures that contractor and grantee performance is in accordance with contractual and assistance commitments; (9) provides leadership and guidance to CDC project officers and program officials; (10) provides leadership, direction, procurement options, and approaches in developing specifications/statements of work and contract awards; (11) plans, directs, coordinates, and conducts the grants management functions and processes in support of assistance awards, including cooperative agreements, discretionary grants, block grants, and formula grants, to state and local governments, universities, colleges, research institutions, hospitals, public and private organizations, small businesses, and minority- and/or women-owned businesses for CDC; (12) participates with top program management in program planning, policy determination, evaluation, and directions concerning acquisition and assistance strategies and execution; (13) maintains branch's official contract and assistance files; (14) maintains a close working relationship with CDC program office components in carrying out their missions; (15) establishes branch goals, objectives and priorities, and assures their consistency and coordination with the overall objectives of PGO.

*Acquisition and Assistance Branch VII (Global) (CAJHU).* This branch supports the Coordinating Office of Global Health and CDC's global acquisition and assistance needs by performing the following: (1) Plans, directs and conducts the acquisition of a wide variety of services, research and development, studies, data collection, equipment, materials, and personal and non-personal services in support of CDC's international operations, utilizing a wide variety of contract types and pricing arrangements; (2) plans, directs, and conducts assistance management activities for CDC's international programs; (3) provides leadership, direction, acquisition options, and approaches in developing

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).

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**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