IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/RegulatoryInformation/Guidances/default.htm* or at *http://www.regulations.gov*.

Dated: April 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07908 Filed 4–8–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0252]

Watson Laboratories, Inc.; Withdrawal of Approval of Bupropion Hydrochloride Extended-Release Tablets, 300 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of Bupropion Hydrochloride (HCl) Extended-Release (ER) Tablets, 300 Milligrams (mg) (Bupropion HCl ER Tablets, 300 mg), under abbreviated new drug application (ANDA) 77–715, held by Watson Laboratories, Inc. (Watson), 4955 Orange Dr., Fort Lauderdale, FL 33314. Watson has voluntarily requested that approval for this product be withdrawn and waived its opportunity for a hearing.

DATES: Effective April 9, 2014.

FOR FURTHER INFORMATION CONTACT: Carolina M. Wirth, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6282, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: FDA approved ANDA 77–715 for Bupropion HCl ER Tablets, 300 mg on June 13, 2007, under section 505(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(j)). Bupropion HCl ER Tablets, 300 mg was indicated for the treatment of major depressive disorder. On September 24, 2013, FDA requested that Watson voluntarily withdraw its Bupropion HCl ER Tablets, 300 mg from the market after results of a bioequivalence study conducted by Watson showed that the firm's Bupropion HCl ER Tablets, 300 mg are not therapeutically equivalent to the 300-mg strength of the reference listed drug. In a letter dated September 30, 2013, Watson requested that FDA withdraw approval of the 300-mg strength of Bupropion HCl ER Tablets, approved under ANDA 77–715, under § 314.150(d) (21 CFR 314.150(d)). In that letter, Watson also waived its opportunity for a hearing. The Agency acknowledged Watson's requests in a letter dated October 4, 2013.

Therefore, under section 505(e) of the FD&C Act (21 U.S.C. 355(e)) and § 314.150(d), and under authority delegated by the Commissioner to the Director, Center for Drug Evaluation and Research, approval of the 300-mg strength of Bupropion HCl Extended-Release Tablets under ANDA 77–715 is withdrawn (see **DATES**). Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: April 3, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07897 Filed 4–8–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Organization, Functions, and Delegations of Authority

Part GFJ

Indian Health Service

Navajo Area Office

Part GFJ, of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), as amended at 52 FR 47053–67, December 11, 1987, as amended at 60 FR 56606, November 9, 1995, as amended at 61 FR 67048, December 19, 1996, as amended at 69 FR 41825, July 12, 2004, as amended at 70 FR 24087, May 6, 2005 70 FR 60350, October 17, 2005, and most recently amended at 71 FR 69570, December 1, 2006, is hereby amended to reflect a reorganization of the Navajo Area Indian Health Service (IHS). The purpose of this re-organization proposal is to update the current approved Navajo Area IHS organization structure due to the decrease in Area shares from Federal facilities transitioning to Public Law 93–638 Indian Self-Determination and Education Assistance Act facilities. Delete the functional statements for the Navajo Area IHS in their entirety and replace with the following:

Organizations and Functions

Department of Health and Human Services
Indian Health Service (G)
Navajo Area Indian Health Service (GFJ)

Office of the Area Director (GFJ1)

(1) Plans, develops and directs the Area Program within the framework of Indian Health Service (IHS) policy in pursuit of the IHS mission; (2) delivers and ensures the delivery of high quality comprehensive health services; (3) coordinates the IHS activities and resources internally and externally with those of other governmental and nongovernmental programs; (4) promotes optimum utilization of health care services through management and delivery of services to American Indians and Alaska Natives; (5) encourages the full application of the principles of Indian preference and Equal Employment Opportunity (EEO); and (6) provides Indian Tribes and other Indian community groups with optional ways of participating in the Indian health programs including an opportunity to participate in developing the mission, values and goals for the Navajo Area Indian Health Service (NAIHS).

Branch of Planning (GFJ1A)

Provides advice on program planning and evaluation activities to include:

(1) Strategic planning coordination at the Area level, including planning, implementing, and monitoring progress on the achievement of the Area Strategic Plan; (2) facilities planning, including the development of program justification documents, program of requirements, quarters justifications, and other required facilities planning and construction documents; (3) staffing requirements and projections for Service Units, facilities projects, and other needs; (4) statistical and epidemiological reporting, analysis, and monitoring, reporting, and including monitoring health status, morbidity, mortality, patient care, health services, health systems, population, demographic, and other health related data for the Area, Service Units, Tribes, States, health programs, universities, researchers, and the general public; (5) developing and implementing data quality improvements and strategies; (6) ensuring resource allocation methodologies are current by updating and providing technical support for resource allocation to the Office of the Area Director (OAD) and the Navajo Area Management Council; (7) providing other program planning and health systems planning activities and technical support to the OAD by