4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0021]

Watson Laboratories, Inc.; Withdrawal of Approval of Abbreviated New Drug Applications for Prescription Pain Medications Containing More than 325 Milligrams of Acetaminophen

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA and Agency) is withdrawing approval of an abbreviated new drug application (ANDA), held by Watson Laboratories, Inc. (Watson), for prescription pain medications that contain more than 325 milligrams (mg) of acetaminophen. Watson has voluntarily requested that approval of this application be withdrawn and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Jane Baluss, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6278, Silver Spring, MD 20993-0002, 301-796-3469.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of January 14, 2011 (76 FR 2691), FDA announced its plans to reduce the maximum dosage unit strength of acetaminophen in prescription drug products. The document announced FDA's conclusion that, based on a reevaluation of the relative risks and benefits of prescription acetaminophen products, fixed-combination prescription drugs containing more than 325 mg of acetaminophen per dosage unit

(tablet or capsule) do not provide a sufficient margin of safety to protect the public against the serious risk of acetaminophen-induced liver injury. Accordingly, we asked product sponsors to limit the maximum amount of acetaminophen per dosage unit to 325 mg and, for those products containing more than 325 mg of acetaminophen per dosage unit, to submit requests that FDA withdraw approval of their applications under § 314.150(d) (21 CFR 314.150(d)). FDA asked that all such requests be made before January 14, 2014, after which date the Agency planned to initiate proceedings under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)). In a *Federal Register* document dated March 27, 2014 (79 FR 17613), FDA withdrew the approval of multiple applications containing more than 325 mg of acetaminophen whose sponsors voluntarily requested withdrawal and waived their opportunity for a hearing on or before that date.

In a letter dated November 22, 2016, Watson voluntarily requested that FDA withdraw approval of its ANDA 074699 for Pentazocine and Acetaminophen Tablets, 25 mg/650 mg, and waived its opportunity for a hearing. The letter also stated that the product was not manufactured or distributed after January 14, 2014.

Therefore, under § 314.150(d), approval of this ANDA, and all amendments and supplements thereto, 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)).

The safety issue discussed in this document and the January 14, 2011, *Federal Register* document is limited to products containing more than 325 mg of acetaminophen per dosage unit. Thus, the withdrawal of approval of this product does not change the approval status of any product with 325 mg or less of acetaminophen per dosage unit that is approved under the same

application, or that refers to or relies on the withdrawn application.

Dated: January 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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