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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-1981-N-0245 (formerly 81N-0080)]

Mepergan Fortis Capsules; Final Decision on Proposal to Refuse Approval of Supplemental New Drug Application; Availability of Final Decision

AGENCY: Food and Drug Administration; HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing that the Initial Decision of the Administrative Law Judge (ALJ), to refuse approval of the supplemental new drug application (sNDA) for Mepergan Fortis Capsules (MFC) (meperidine HCl, promethazine HCl), is the final decision of the Commissioner by operation of law. In the Initial Decision, the ALJ found that MFC had not been shown to be supported by substantial evidence consisting of adequate and well-controlled studies to be effective for sedation and analgesia in patients with concurrent moderate pain and apprehension, such as postoperative and post-trauma patients with those symptoms; that the drug did not satisfy the combination drug policy; and that it is a "new drug." The sNDA applicant filed exceptions to the ALJ's Initial Decision. FDA recently requested that the current owner of the sNDA application affirm its desire to pursue the appeal of the ALJ's Initial Decision; however, the applicant did not affirm its desire to pursue the appeal within the specified timeframe. Accordingly, FDA now deems those exceptions as withdrawn. Consequently, the proceeding is in the same procedural position as if no exceptions to the ALJ's Initial Decision had been filed; therefore, the ALJ's Initial Decision has become the final decision of the Commissioner by operation of law.

DATES: This final decision is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: For access to the docket, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 240-402-5931.

SUPPLEMENTARY INFORMATION:

I. Background

In 1962, the Federal Food, Drug, and Cosmetic Act (the FD&C Act) was amended by the Drug Amendments Act of 1962, and these amendments provided that new drugs could no longer be approved unless both safety and efficacy had been established for them. As amended, the FD&C Act also required FDA to evaluate drugs approved as safe between 1938 and 1962 to determine whether such drugs were effective and to withdraw approval for any new drug application (NDA) where there was not substantial evidence of the drug's effectiveness. The person contesting the withdrawal of the approval had the burden of coming forward with evidence of effectiveness for the drug. FDA's review of these pre-1962 drugs is known as the Drug Efficacy Study Implementation (DESI) program.

In a document published in the *Federal Register* of April 20, 1972 (37 FR 7827), after evaluating reports received from the National Academy of Sciences/National Research Council,

Drug Efficacy Study Group, and other available evidence, FDA classified MFC as "possibly effective" for moderate to moderately severe pain. This document also stated that no NDA had been approved or deemed approved for MFC and that additional evidence needed to be submitted to FDA to establish MFC's effectiveness. Thereafter, Wyeth, a division of American Home Products (Wyeth), submitted a supplement to its approved NDA 11-730 (Mepergan Injection) for MFC (NDA 11-730, S-003). In a document published in the *Federal Register* of September 18, 1981 (46 FR 46404), the Director of the Bureau of Drugs (now the Center for Drug Evaluation and Research) proposed to refuse approval of the sNDA and offered Wyeth the opportunity for a hearing.

Wyeth submitted its request for a hearing and, by a document published in the *Federal Register* of December 31, 1984 (49 FR 50788), the Office of the Commissioner granted the hearing request. Following the submission of written testimony and documentary evidence, an ALJ, Daniel J. Davidson, conducted a hearing from January 14 to 17, 1986. He issued his Initial Decision on December 4, 1987. The ALJ found that: (1) the effectiveness of MFC had not been proven by substantial evidence of adequate and well-controlled clinical trials, (2) the requirements of the combination drug policy had not been met, and (3) MFC is a new drug under 21 U.S.C. 321(p). Wyeth timely appealed the ALJ's Initial Decision by filing exceptions with the Commissioner under 21 CFR 12.125.

On August 23, 2017, FDA sent a letter to West-Ward Pharmaceuticals Corporation (West-Ward), successor to Wyeth, to determine whether West-Ward remained interested in pursuing its appeal of the ALJ's Initial Decision. FDA informed the company that if it did not respond and affirm its desire to pursue its appeal by September 21, 2017, the Office of the Commissioner would conclude that West-Ward no longer wishes to pursue the appeal of the

ALJ's Initial Decision and will proceed as if the appeal has been withdrawn. The Office of the Commissioner did not receive a response from West-Ward by the given date; therefore, the Commissioner now deems the exceptions withdrawn.

II. Conclusion and Order

Given that the exceptions have been deemed withdrawn, this proceeding is now in the same procedural posture as if no exceptions had ever been filed. When parties do not file exceptions to the ALJ's Initial Decision, and the Commissioner does not file a notice of review, the ALJ's Initial Decision becomes the final decision of the Commissioner (see 21 CFR 12.120(e)). FDA will publish a notice in the *Federal Register* when an initial decision becomes the final decision of the Commissioner without appeal to or review by the Commissioner (see 21 CFR 12.120(f)).

Therefore, the ALJ's Initial Decision is the final decision of the Commissioner effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Pursuant to the findings in the ALJ's Initial Decision, under section 505(d) of the FD&C Act (21 U.S.C. 355(d)) and under the authority delegated by the Secretary of Health and Human Services, the Commissioner finds that there is a lack of substantial evidence that MFC will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling for sedation and analgesia in patients with concurrent moderate pain and apprehension, such as postoperative and post-trauma patients with those symptoms. The Commissioner further finds that MFC does not meet the combination drug policy in 21 CFR 300.50 and that it is a "new drug" within the meaning of 21 U.S.C. 321(p). Therefore, approval of the sNDA for MFC is denied. Distribution of products subject to the ALJ's Initial Decision in interstate commerce

without an approved application is prohibited and subject to regulatory action (see, e.g., sections 505(a) and 301(d) (21 U.S.C. 331(d)) of the FD&C Act).

The full text of the ALJ's Initial Decision may be seen in the Dockets Management Staff and in this docket (see ADDRESSES).

Dated: November 7, 2017.

Denise Hinton,

Acting Chief Scientist.

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