4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-P-0649]

Determination That QUESTRAN (Cholestyramine for Oral Suspension, USP), Equivalent to 4 Grams, and QUESTRAN LIGHT (Cholestyramine for Oral Suspension, USP), Equivalent to 4 Grams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that QUESTRAN (cholestyramine for oral suspension, USP), equivalent to (EQ) 4 grams (g), and QUESTRAN LIGHT (cholestyramine for oral suspension, USP), EQ 4 g, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of the abbreviated new drug applications (ANDAs) that refer to these drugs, and it will allow FDA to approve ANDAs that refer to these drugs as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

QUESTRAN (cholestyramine for oral suspension, USP), EQ 4 g, is the subject of NDA 16-640, held by Bristol-Myers Squibb, and initially approved on August 3, 1973. QUESTRAN LIGHT (cholestyramine for oral suspension, USP), EQ 4 g, is the subject of NDA 19-669, also held by Bristol-Myers Squibb, and initially approved on December 5, 1988. QUESTRAN and QUESTRAN LIGHT are indicated as adjunctive therapy for the reduction of elevated serum cholesterol in patients with primary hypercholesterolemia (elevated low-density lipoprotein cholesterol) who do not respond adequately to diet.

In a letter dated May 31, 2012, Bristol-Myers Squibb notified FDA that QUESTRAN (cholestyramine for oral suspension, USP), EQ 4 g, and QUESTRAN LIGHT (cholestyramine for oral suspension, USP), EQ 4 g, were being discontinued, and FDA moved the drug products to the "Discontinued Drug Product List" section of the Orange Book. Lachman Consultant Services, Inc., submitted a citizen petition dated June 19, 2012 (Docket No. FDA-2012-P-0649), under 21 CFR 10.30, requesting that the Agency determine whether QUESTRAN (cholestyramine for oral suspension, USP), EQ 4 g, was withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address QUESTRAN LIGHT, that version of the drug product has also been discontinued. On our own initiative, we have also determined whether QUESTRAN LIGHT was withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that QUESTRAN (cholestyramine for oral suspension, USP), EQ 4 g, and QUESTRAN LIGHT (cholestyramine for oral suspension, USP), EQ 4 g, were not withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of QUESTRAN (cholestyramine for oral suspension, USP), EQ 4 g, and QUESTRAN LIGHT (cholestyramine

for oral suspension, USP), EQ 4 g, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that either product was withdrawn from sale for reasons of safety or effectiveness. Moreover, the petitioner has identified no data or other information suggesting that QUESTRAN (cholestyramine for oral suspension, USP), EQ 4 g, was withdrawn for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list QUESTRAN (cholestyramine for oral suspension, USP), EQ 4 g, and QUESTRAN LIGHT (cholestyramine for oral suspension, USP), EQ 4 g, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of the approved ANDAs that refer to QUESTRAN or QUESTRAN LIGHT. Additional ANDAs for cholestyramine and cholestyramine light for oral suspension, USP, EQ 4 g, may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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