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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99P-4848]

Determination That Carbinoxamine Maleate 4 Milligrams per 5 Cubic Centimeters Elixir Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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(FDA) has determined that carbinoxamine maleate (Clistin) 4 milligrams (mg) per 5 cubic centimeters (cc) elixir was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDA's) for carbinoxamine maleate 4 mg per 5 cc elixir.

FOR FURTHER INFORMATION CONTACT: Mary E. Catchings, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 301-594-2041.

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 approved under an ANDA procedure. ANDA sponsors 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. Sponsors of ANDA's 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.

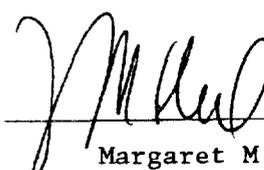
The 1984 amendments included what is now section 505(j)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(6)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products with Therapeutic Equivalence Evaluations,” generally known as the “Orange Book.” Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the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). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)) the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

In a citizen petition dated October 8, 1999 (Docket No. 99P-4848/CP1), submitted under 21 CFR 314.122, Mikart, Inc., requested that the agency determine whether carbinoxamine maleate (Clistin) 4 mg per 5 cc elixir was withdrawn from sale for reasons of safety or effectiveness. Carbinoxamine maleate (Clistin) 4 mg per 5 cc elixir was the subject of approved NDA 8-955. In the **Federal Register** of April 5, 1985 (50 FR 13661), FDA withdrew approval of NDA 8-955 for Clistin Elixir after McNeil Pharmaceutical notified the agency that Clistin Elixir was no longer being marketed under NDA 8-955 and requested the withdrawal of that application.

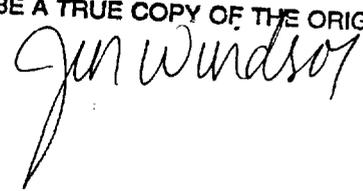
FDA has reviewed its records and, under § 314.161, has determined that carbinoxamine maleate 4 mg per 5 cc elixir was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will list carbinoxamine maleate 4 mg per 5 cc elixir in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” identifies, among other items, drug products that have been discontinued from marketing for reasons other

than safety or effectiveness. ANDA's that refer to carbinoxamine maleate 4 mg per 5 cc elixir as the listed drug may be approved by the agency.

Dated: 4/3/00
April 3, 2000



Margaret M. Dotzel
Acting Associate Commissioner for Policy

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