DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004F–0546]

Alltech, Inc.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 2253) proposing that the food additive regulations be amended to provide for the safe use of polyurethane polymer coating in ruminant feed.

FOR FURTHER INFORMATION CONTACT: Isabel Pocurull, Center for Veterinary Medicine (HFV–226), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6853, e-mail: *isabel.pocurull@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of January 13, 2005 (70 FR 2415), FDA announced that a food additive petition (FAP 2253) had been filed by Alltech, Inc., 3031 Catnip Hill Pike, Nicholasville, KY 40356. The petition proposed to amend the food additive regulations in part 573 (21 CFR part 573) to provide for the safe use of polyurethane polymer coating in ruminant feed. Alltech, Inc., has now withdrawn the petition without prejudice to a future filing (21 CFR 571.7).

Dated: June 1, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E6–8982 Filed 6–8–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0229]

Carbinoxamine Products; Enforcement Action Dates

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to take enforcement action against unapproved drug products containing carbinoxamine and persons who cause the manufacture of such products. Numerous drug products containing carbinoxamine are marketed without approved applications and many are inappropriately labeled for use in infants and young children. Drug products containing carbinoxamine are new drugs that require approved applications. One firm has approved applications to market products containing carbinoxamine. In addition, there is information showing that carbinoxamine should not be used in children under 2 years of age. Manufacturers who wish to market carbinoxamine products that do not already have FDA approval must obtain FDA approval of a new drug application (NDA) or an abbreviated new drug application (ANDA). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance entitled ''Marketed Unapproved Drugs—Compliance Policy Guide.''

DATES: This notice is effective June 9, 2006.

For marketed, unapproved carbinoxamine-containing drug products that have a National Drug Code (NDC) number that is listed with FDA on the effective date of this notice (i.e., ''currently marketed products''), however, the agency intends to exercise its enforcement discretion to permit products properly marketed with those NDC numbers a brief period of continued marketing after June 9, 2006 as follows. Any firm manufacturing such an unapproved drug product containing carbinoxamine that is labeled for use in children less than 2 years of age or marketed as drops for oral administration may not manufacture that product on or after July 10, 2006. Any firm manufacturing any other such unapproved drug product containing carbinoxamine may not manufacture that product on or after September 7, 2006. Unapproved drug products containing carbinoxamine that are not currently marketed and listed with the agency on the date of this notice must, as of the date of this notice, have approved applications prior to their introduction into interstate commerce.

ADDRESSES: All communications in response to this notice should be identified with Docket No. 2006N–0229 and directed to the appropriate office listed as follows:

Regarding applications under section 505(j) of the Federal Food, Drug, and Cosmetic Act (the act)(21 U.S.C. 355(j)): Office of Generic Drugs (HFD–600), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

Regarding applications under section 505(b) of the act: Division of Pulmonary and Allergy Products, Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Silver Spring, MD 20993–0002.

All other communications: John Loh, Division of New Drugs and Labeling Compliance, Center for Drug Evaluation and Research (HFD–310), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John Loh, Division of New Drugs and Labeling Compliance, Center for Drug Evaluation and Research (HFD–310), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–8965, e-mail: *John.Loh@FDA.HHS.GOV*.

SUPPLEMENTARY INFORMATION:

I. Background

A. The DESI Review

When initially enacted in 1938, the act required that ''new drugs'' be approved for safety by FDA before they could legally be sold in interstate commerce. To this end, the act made it the sponsor's burden to show FDA that its drug was safe through the submission of an NDA. Between 1938 and 1962, if a drug obtained approval, FDA considered drugs that were identical, related, or similar (IRS)[1] to the approved drug to be ''covered'' by that approval, and allowed those IRS drugs to be marketed without independent approval.

In 1962, Congress amended the act to require that new drugs also be proven effective for their labeled indications, as well as safe. This amendment also required FDA to conduct a retrospective evaluation of the effectiveness of the drug products that FDA had approved as safe between 1938 and 1962. FDA contracted with the National Academy of Science/National Research Council (NAS/NRC) to make an initial evaluation of the effectiveness of over 3,400 products that were approved only for safety. The NAS/NRC reports for these drug products were submitted to FDA in the late 1960s and early 1970s. The agency reviewed and re-evaluated the reports and published its findings in **Federal Register** notices. FDA's

[1] Section 310.6(b)(1) (21 CFR 310.6(b)(1)) provides: ''An identical, related, or similar drug includes other brands, potencies, dosage forms, salts, and esters of the same drug moiety as well as of any drug moiety related in chemical structure or known pharmacological properties.''