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Caller	A. Corbin

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0143]

High Chemical Co. et al.; Proposal to Withdraw Approval of 13 New Drug Applications; Opportunity for a Hearing; Reissuance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reissuance.

SUMMARY: The Food and Drug Administration (FDA) is reissuing the notice announcing an opportunity to request a hearing on the agency's proposal to withdraw approval of 13 new drug applications (NDAs) from multiple sponsors. The basis for the proposal is that the sponsors have repeatedly failed to file required annual reports for these applications. In the FEDERAL REGISTER of January 28, 2005 (70 FR 4134), FDA published a notice announcing an opportunity for a hearing on the agency's proposal to withdraw approval of 13 NDAs from multiple sponsors. That notice published with an inadvertent error; in a document published elsewhere in this issue of the FEDERAL REGISTER, the agency is withdrawing that notice.

DATES: Submit written requests for a hearing by [insert date 30 days after date of publication in the FEDERAL REGISTER]; submit data and information in support of the hearing request by [insert date 60 days after date of publication in the FEDERAL REGISTER].

ADDRESSES: Requests for a hearing, supporting data, and other comments are to be identified with Docket No. 2005N-0143 to be

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submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Florine P. Purdie  
Center for Drug Evaluation and Research (HFD-7),  
Food and Drug Administration,  
5600 Fishers Lane,  
Rockville, MD 20857,  
301-594-2041.

SUPPLEMENTARY INFORMATION: FDA is reissuing the notice announcing an opportunity to request a hearing on the agency's proposal to withdraw approval of 13 new drug applications (NDAs) from multiple sponsors. The basis for the proposal is that the sponsors have repeatedly failed to file required annual reports for these applications. In the FEDERAL REGISTER of January 28, 2005 (70 FR 4134), FDA published a notice announcing an opportunity for a hearing on the agency's proposal to withdraw approval of 13 NDAs from multiple sponsors. That notice published with an inadvertent error; in a document published elsewhere in this issue of the FEDERAL REGISTER, the agency is withdrawing that notice.

The holders of approved applications to market new drugs for human use are required to submit annual reports to FDA concerning

each of their approved applications in accordance with § 314.81 (21 CFR 314.81). The holders of the approved applications listed in the following table have failed to submit the required annual reports and have not responded to the agency's request by certified mail for submission of the reports.

Application No.	Drug	Applicant
NDA 0-763	Sterile Solution Procaine Injection 2% (Procaine Hydrochloride (HCl))	High Chemical Co., 1760 N. Howard St., Philadelphia, PA 19122
NDA 2-959	Nicotinic Acid (Niacin) Tablets	The Blue Line Chemical Co., 302 South Broadway, St. Louis, MO 63102
NDA 4-236	Sherman (thiamine HCl) Elixir	Do.
NDA 4-368	Ascorbic Acid Tablets	Do.
NDA 5-159	D.S.D. (diethylstilbestrol dipropionate)	Do.
NDA 9-452	Multifuge (piperazine citrate) Syrup	Do.
NDA 10-055	Fire Gard Three-Alarm Burn Relief (Methylcellulose)	Gard Products, Inc., 2560 Tara Lane, Brunswick, GA 31520
NDA 10-337	Fling Antiperspirant Foot Powder	Bauer & Black, A Division of The Kendall Co., One Federal St., Boston, MA

Application No.	Drug	Applicant
		02110
NDA 10-541	BY-NA-MID (Butylphenamide or B and Zinc Oxide or Stearate) Tincture, Ointment, Lotion, and Powder	Miles, Inc., Cutter Biological, P.O. Box 1986, Berkeley, CA 94701
NDA 10-823	BIKE Foot and Body Powder	Bauer & Black, A Division of The Kendall Co.
NDA 10-824	BIKE Anti-Fungal Aerosol Spray	Do.
NDA 11-233	TKO with Entrin Roll-On Liquid	Modern-Labs, Inc., Maple Rd., Gambrills, MD 21504
NDA 19-432	Spectamine (Iofetamine Hydrochloride I-123) Injection	IMP, Inc., 8050 El Rio, Houston, TX 77054

Therefore, under § 314.150(b)(1) (21 CFR 314.150(b)(1)) and § 314.200 (21 CFR 314.200), notice is given to the holders of the approved applications listed in the table and to all other interested persons that the Director of the Center for Drug Evaluation and Research proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) withdrawing approval of the applications and all amendments and supplements thereto on the ground that the applicants have failed to submit reports required under § 314.81.

In accordance with section 505 of the act and part 314 (21

CFR part 314), the applicants are hereby provided an opportunity to request a hearing to show why the applications listed previously should not be withdrawn.

An applicant who decides to seek a hearing shall file:

(1) On or before [insert date 30 days after date of publication in the FEDERAL REGISTER], a written notice of participation and request for a hearing, and (2) on or before [insert date 60 days after date of publication in the FEDERAL REGISTER], the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation and request for a hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 and in part 12 (21 CFR part 12).

The failure of an applicant to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that applicant not to avail itself of the opportunity to request a hearing concerning the proposal to withdraw approval of the applications and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the applications and the drug products may not thereafter lawfully be marketed, and FDA will begin appropriate regulatory action to

remove the products from the market. Any new drug product marketed without an approved new drug application is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. Reports submitted to remedy the deficiencies must be complete in all respects in accordance with § 314.81. If the submission is not complete or if a request for a hearing is not made in the required format or with the required reports, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing must be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 505 (21 U.S.C. 355)) and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner.

Dated: 4/5/05  
April 5, 2005.



Steven Galson,  
Acting Director,  
Center for Drug Evaluation and Research.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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