Medicare & Medicaid Services, 7500 Security Blvd, Baltimore, MD 21244.

Presentations and Comments: Interested persons may present data, information, or views orally or in writing on issues pending before the Committee. Please submit written comments to Kimberly Long, by e-mail at *klong@cms.hhs.gov* or by mail to the Executive Secretary for MCAC, Coverage and Analysis Group, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C1–09–06, Baltimore, MD 21244.

Web site: You may access up-to-date information on this meeting at *www.cms.hhs.gov/mcac/default.asp#meetings.*

Hotline: You may access up-to-date information on this meeting on the CMS Advisory Committee Information Hotline, 1–877–449–5659 (toll free) or in the Baltimore area (410) 786–9379.

FOR FURTHER INFORMATION CONTACT: Kimberly Long, Executive Secretary, by telephone at 410–786–5702 or by e-mail at *klong@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION: On December 14, 1998, we published a notice in the **Federal Register** (63 FR 68780) to describe the Medicare Coverage Advisory Committee (MCAC), which provides advice and recommendations to us about clinical issues. This notice announces a public meeting of the Committee.

Meeting Topic: The Committee will discuss evidence, hear presentations and public comment and make recommendations regarding the standard treatment of chronic wounds. Discussion will address such usual care treatment as cleansing, debridement, dressings, compression, off-loading and antibiotics. Members will also review factors necessary for quality clinical trials that address other wound healing technologies. The Committee will not discuss other treatments that may be used when wounds do not heal.

Background information about this topic, including panel materials, is available on the Internet at *http://www.cms.hhs.gov/coverage/.*

Procedure: This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. The Committee may limit the number and duration of oral presentations to the time available. If you wish to make formal presentations, you must notify the Executive Secretary named in the **FOR FURTHER INFORMATION CONTACT** section and submit the following by the *Deadline for Presentations and Comments* date listed in the **DATES** section of this notice: a brief statement of the general nature of the evidence or arguments you wish to present, and the names and addresses of proposed participants. A written copy of your presentation must be provided to each Committee member before offering your public comments. Your presentation must address the questions asked by CMS to the Committee. The questions will be available on our Web site at *http://www.cms.hhs.gov/mcac/default.asp* meetings. If the specific questions are not addressed, your presentation will not be accepted. We request that you declare at the meeting whether or not you have any financial involvement with manufacturers of any items or services being discussed (or with their competitors).

After the public and CMS presentations, the Committee will deliberate openly on the topic. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15-minute unscheduled open public session for any attendee to address issues specific to the topic. At the conclusion of the day, the members will vote and the Committee will make its recommendation.

Registration Instructions

The Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register by contacting Maria Ellis at 410–786–0309, mailing address: Coverage and Analysis Group, OCSQ; Centers for Medicare & Medicaid Services; 7500 Security Blvd, Mailstop: C1–09–06; Baltimore, MD 21244, or by e-mail at *Mellis@cms.hhs.gov.* Please provide your name, address, organization, telephone and fax number, and e-mail address.

You will receive a registration confirmation with instructions for your arrival at the CMS complex. You will be notified if the seating capacity has been reached.

Because the meeting is located on Federal property, for security reasons, any persons wishing to attend this meeting must register by close of business on January 17, 2005. In order to gain access to the building and grounds, participants must show to the Federal Protective Service or guard service personnel, government-issued photo identification and a copy of their registration confirmation. Individuals who have not registered in advance will not be allowed to enter the building to attend the meeting.

Authority: 5 U.S.C. App. 2, section 10(a).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 21, 2005.

Sean R. Tunis,

Director, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services.

[FR Doc. 05–1503 Filed 1–27–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0010]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for 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.

DATES: Submit written requests for a hearing by February 28, 2005; submit data and information in support of the hearing request by March 29, 2005.

ADDRESSES: Requests for a hearing, supporting data, and other comments are to be identified with Docket No. 2005N–0010 and 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: 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 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, 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 21 CFR part 314, the applicants are hereby provided an opportunity for a hearing to show why the applications listed previously should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products covered by these applications.

An applicant who decides to seek a hearing shall file: (1) A written notice of participation and request for a hearing (see **DATES**) and (2) the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing (see **DATES**). Any other interested person may also submit comments on this document. 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 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 for 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 NDA 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 (the Commissioner) 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 section 301 of the act (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 act (section 505 (21 U.S.C. 355)) and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner.

Dated: January 19, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–1656 Filed 1–27–05; 8:45 am]

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