

[DESI 9206; Docket No. FDC-D-414; NDA Nos. 9-205, 10-431]

TORCH LABORATORIES, INC., AND ABBOTT LABORATORIES

Tellurium Dioxide Suspension; and Selenium Sulfide With Hydrocortisone Acetate Ointment; Notice of Opportunity for Hearing on Proposal To Withdraw Approval of New Drug Applications

In a notice (DESI 9206) published in the FEDERAL REGISTER of July 30, 1970 (35 F.R. 12234), the Commissioner of Food and Drugs announced his conclusions pursuant to the evaluation of reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following drugs, stating that the drugs were regarded as possibly effective for the labeled indications.

NDA 9-205; (previously incorrectly identified as NDA 9-206); Teles Suspension Torch containing tellurium dioxide; Torch Laboratories, Inc., 542 Industrial Park Drive, Yeading, Pa. 19051.

NDA 10-431; Selsunef Ointment containing selenium sulfide and hydrocortisone acetate; Abbott Laboratories, 14th and Sheridan Road, North Chicago, Ill. 60064.

Information subsequently presented to the Food and Drug Administration concerning Teles Suspension Torch was found not to provide substantial evidence of effectiveness.

Both of the drugs have been reclassified as lacking substantial evidence of effectiveness in that such evidence has not been submitted.

Therefore, notice is given to the holders of the new drug applications, and to any interested person who may be adversely affected, that the Commissioner proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) withdrawing approval of the listed new drug applications and all amendments and supplements thereto on the grounds that new information before him with respect to the drugs, evaluated together with the evidence available to him when the applications were approved, shows there is a lack of substantial evidence that the drugs will have all the effects they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling.

In accordance with the provisions of section 505 of the Act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR Part 130), the Commissioner will give the applicants, and any interested person who would be adversely affected by an order withdrawing such approval, an opportunity for a hearing to show why approval of the new drug applications should not be withdrawn. Any related drug for human use, not the subject of an approved new drug application, may be affected by this action.

Within 30 days after publication here-in in the FEDERAL REGISTER such persons are required to file with the Hearing

Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852, a written appearance electing whether:

1. To avail themselves of the opportunity for a hearing; or
2. Not to avail themselves of the opportunity for a hearing.

If such persons elect not to avail themselves of the opportunity for a hearing, the Commissioner without further notice will enter a final order withdrawing approval of the new drug application. Failure of such persons to file a written appearance of election within said 30 days will be construed as an election by such persons not to avail themselves of the opportunity for a hearing.

The hearing contemplated by this notice will be open to the public except that any portion of the hearing that concerns a method or process the Commissioner finds entitled to protection as a trade secret will not be open to the public, unless the respondent specifies otherwise in his appearance.

If such persons elect to avail themselves of the opportunity for a hearing, they must file, within 30 days after publication of this notice in the FEDERAL REGISTER, a written appearance requesting the hearing, giving the reasons why approval of the new drug application should not be withdrawn, together with a well-organized and full-factual analysis of the clinical and other investigational data they are prepared to prove in support of their opposition. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that a genuine and substantial issue of fact requires a hearing. When it clearly appears from the data in the application and from the reasons and factual analysis in the request for the hearing that no genuine and substantial issue of fact precludes the withdrawal of approval of the application, the Commissioner will enter an order on these data, making findings and conclusions on such data.

If a hearing is requested and justified by the response to this notice, the issues will be defined, a hearing examiner will be named, and he shall issue, as soon as practicable after the expiration of such 30 days, a written notice of the time and place at which the hearing will commence (35 F.R. 7250, May 8, 1970; 35 F.R. 16631, Oct. 27, 1970).

Received requests for a hearing and/or elections not to request a hearing may be seen in the Office of the Hearing Clerk (address given above) during regular business hours, Monday through Friday.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052-53, as amended; 21 U.S.C. 355) and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: March 16, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

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**Office of the Secretary
OFFICE OF PROCUREMENT AND
MATERIEL MANAGEMENT**

**Statement of Organization, Functions,
and Delegation of Authority**

Part 1 of the Statement of Organization, Functions, and Delegation of Authority for the Department of Health, Education, and Welfare, Office of the Secretary, is amended to add a new section 1U14, *Office of Procurement and Materiel Management*. The text of the new section reads as follows:

SEC. 1U14.00 Mission. The Office of Procurement and Materiel Management provides staff support and technical assistance to the Office of the Secretary and operating agencies, and directs comprehensive evaluations of departmental procurement and materiel activities.

SEC. 1U14.10 Organization. A. The Director, Office of Procurement and Materiel Management, reports to the Deputy Assistant Secretary for Administration.

B. The Office of Procurement and Materiel Management consists of the following:

- Procurement Management Division;
- Materiel Management Division.

These Divisions, each of which is headed by a director reporting to the Director, OPMM, are organized to provide their specialized support and assistance to operating activities throughout the Department.

SEC. 1U14.20 Functions. A. The Office of Procurement and Materiel Management provides departmental staff support in the areas of procurement and materiel management, as follows:

1. Provides support and technical assistance to the Office of the Secretary and to the operating agencies.
2. Evaluates activities.
3. Directs and provides departmental training.
4. Compiles, analyzes, and distributes data for use by DHEW management, the Congress, and other Government agencies.
5. Provides liaison with other Government agencies and the Congress.

B. Procurement Management Division.

1. Develops and issues departmental policies, regulations, and procedures pertaining to the procurement of personal property and nonpersonal services.

2. Plans, provides leadership, conducts, and reports on scheduled and special studies. This includes: Determining compliance with existing statutes and policies and procedures or regulations; evaluating and reporting on effectiveness of operating activities; making recommendations for corrections and improvements; following up and reporting on action taken to effectuate recommendations; developing and installing new, revised, or standard systems of operation.