

Tab 102

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

*Rec'd 7/11/01*

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DATE: JUN 25 2001

FROM: Consumer Safety Officer  
Non-Traditional Drug Compliance Team, HFD-314  
Division of Labeling and Nonprescription Drug Compliance, HFD-310  
Office of Compliance  
Center for Drug Evaluation and Research

THRU: Acting Director *William T. Ryzel*  
Division of Labeling and Nonprescription Drug Compliance, HFD-310  
Office of Compliance

SUBJECT: NYK-DO Seizure Recommendation Dated June 13, 2001  
137015/16/17, T2 Pro-Thyroid Formula

TO: Director,  
Division of Compliance Management and Operations, HFC-210

**Firms:** **Distributor:**  
Biotest Laboratories, LLC  
2155 Reliable Circle  
P.O. Box 60310  
Colorado Springs, CO 80906

and

**Contract Manufacturer:**  
Phoenix Laboratories, Inc.  
140 Lauman Lane  
Hicksville, NY 11801

SEIZURE APPROVED MEMORANDUM

CENTER CONTACTS

William Russell, HFD-314, 301-827-7369

## SUMMARY OF DECISION

The CDER Office of Compliance concurs with the June 13, 2001, New York District Recommendation that three in-process batches of the firm's product T2 Pro-Thyroid Formula consisting of nine drums of bulk in-process product, one drum of 1% L-thyronine triturate, and Pro-Thyroid labels be seized at Phoenix Laboratories, Inc. This firm is the custom manufacturer of T2 Pro-Thyroid Formula for Biotest Laboratories. The triturate is a mixture of 3,5-diiodo-L-thyronine and microcrystalline cellulose. The action is based on new drug [505(a)] and misbranded drug [502(f)(1)] charges. Further, the District has recommended food adulteration charges [402(f)(1)(A) and (a)(1)] in the alternative. We defer to CFSAN and the Office of Chief Counsel for these charges. According to the recommendation, the District forwarded a copy of the action to CFSAN for concurrent review.

## REASON FOR SEIZURE

Evaluation by representatives of CDER's Division of Metabolic and Endocrine Drug Products, HFD-510, indicates that T2 Pro-Thyroid Formula, containing 3,5-diiodo-L-thyronine, poses a class 1 health hazard and is likely to cause injury or death. In addition, a review of the product by CFSAN reveals T2 Pro-Thyroid Formula is not a dietary supplement. Therefore, the structure/function claims related to fat loss and thyroid function found on the firm's web site cause the product to be a drug within the meaning of 201(g)(1)(C). The health hazard evaluation and CFSAN's review were attachments to the CDER seizure recommendation approval dated June 7, 2001, pertaining to

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finished product T2 Pro-Thyroid Formula and bulk 3,5-diiodo-L-thyronine, located at Biotest Laboratories, Colorado Springs, CO. They are also provided as attachments under tab "H" of the current seizure recommendation.

### **SEIZURE APPROVED**

In-Process T2 Pro-Thyroid Formula, Bulk L-Thyronine Triturate, and Finished Product Labels (T2 Pro-Thyroid Formula)

355(a)-product is an unapproved new drug.

352(f)(1)-product lacks adequate directions for use.

### **CHARGES ADDED**

We have added a 505(a) charge to this action as we did in the previously mentioned seizure approval dated June 7, 2001. We discussed adding this charge to the previous seizure with the Office of the Chief Counsel, Bill McConagha. Bill informed us that he tentatively supports including the new drug charge to the previous seizure in part because the firm's web site is identified on the finished product label and therefore we are in a potentially better position to define the Internet as labeling. The previous seizure included both finished product and bulk product. Although no finished product is a part of the current seizure, the action includes finished product labels for the T2 Pro-Thyroid Formula. This label includes the Biotest web site. We are able to associate the Biotest web site, where the claims are made, with the bulk and, thereby, consider it labeling for the bulk. We defer,

however, to the Office of the Chief Counsel the decision of whether this is a legally supportable position. If the Office of the Chief Counsel concurs, the Complaint should be modified by adding the following paragraph, "The article is a drug within the meaning of the Act, 21 U.S.C. 321(g)(1), that may not be introduced or delivered for introduction into interstate commerce pursuant to 21 U.S.C. 355(a) because it is a new drug within the meaning of 21 U.S.C. 321(p) and no approval of an application filed pursuant to 21 U.S.C. 355(b) is in effect for such drug.", or a paragraph of similar language. Further, the letter to the United States Attorney should also be modified by adding language that discusses the new drug status of the product.

#### **EXPERT WITNESSES**

Dr. Jean Temeck, Medical Officer in the Division of Metabolic and Endocrine Drug Products, and David Orloff, M.D., Director of the Division, concluded that the product, T2 Pro-Thyroid Formula, poses a significant health hazard. These medical officers would serve as our expert witnesses in the event of trial. Further, Dr. Lori Love, HFS-805, in a previous review for the product, Lipokinetix, which also contained diiodothyronine, indicated that this ingredient represents a significant and unreasonable risk of illness or injury. Therefore, Dr. Love may be able to play a role in support of this action, if necessary. (See Attachment C, Exhibit 2 in the June 7, 2001, approval memo for Dr. Love's review).

#### **ISSUES AND COMMENTS**

There was no prior Warning Letter issued because this product is a Class I health hazard. Furthermore, the firm was made aware of the health hazard associated with this ingredient, and agreed to voluntarily hold the in-process batches.

#### **ADDITIONAL COMMENTS**

As in the previous seizure approval dated June 7, 2001, we are including an unapproved new drug charge in this action based on structure/function claims found on the firm's Internet web site. Even though the product cited in this seizure recommendation is bulk, finished product labels are in the proximity and intended for the finished product. These labels bear the firm's web site address. Even though the finished product container labels bear no claims, the labels provide instructions to consumers with: "Questions or comments? Call or go online at: 800-525-1940 /biotest-online.com." Accessing the Internet address (biotest-online.com) takes consumers to web pages of information on the firm's products and claims for these products. The claims for T2 Pro-Thyroid Formula includes, "... without a doubt, the single, most potent compound for fat loss ..." and "...maximize thyroid function...." A review of the product by CFSAN determined the product is not a dietary supplement. Therefore, these structure/function claims cause the product to be a drug within the meaning of section 201(g)(1)(C) of the Act.

New York District provided what appear to be "new" product labels that contain a new website "BiotestEdge.com." The entry of "BiotestEdge.com" as an address takes the consumer to the previously cited "biotest-online" website and the claims found on that website have not been

changed.

At this time we do not support the inclusion of the 502(j) charge mentioned on page 3 of the New York District's cover memo. With the addition of the 505(a) charge, the 502(j) charge significantly adds to our burden of proof and is unnecessary. If, however, the Office of the Chief Counsel does not believe the 505(a) charge is supportable, we would reconsider supporting the 502(j) charge.

We have supplied language for inclusion of the 505(a) charge in the Complaint. We defer all other changes to these documents to your office and the Office of the Chief Counsel.



William Russell