

Tab 103

## Goldwitz, Bruce A

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**From:** Goldwitz, Bruce A  
**Sent:** Tuesday, September 04, 2001 2:12 PM  
**To:** Thomas, Edward W  
**Subject:** RE: Tom Mooney Did a Good Job

Ed,

After receiving Eric Blumberg's 8/13/2001 e-mail conditionally approving the seizure.

Bruce Goldwitz

-----Original Message-----

**From:** Thomas, Edward W  
**Sent:** Wednesday, August 22, 2001 8:16 AM  
**To:** Goldwitz, Bruce A  
**Subject:** RE: Tom Mooney Did a Good Job

at what point of review was this seizure when the availability check was requested?

-----Original Message-----

**From:** Goldwitz, Bruce A  
**Sent:** Tuesday, August 21, 2001 1:47 PM  
**To:** Thomas, Edward W  
**Subject:** FW: Tom Mooney Did a Good Job

FYI

-----Original Message-----

**From:** Goldwitz, Bruce A  
**Sent:** Monday, August 20, 2001 2:18 PM  
**To:** Vitillo, Otto D  
**Cc:** Woyshner, Jerome G  
**Subject:** Tom Mooney Did a Good Job

Otto,

Confirming our conversation today. As you know, Tom Mooney did a 5/31-6/5/2001 inspection at Phoenix Laboratories, Inc. in Hicksville, NY. Tom documented the firm's contract manufacture of T2 Pro-Thyroid Formula, a unapproved and misbranded drug and adulterated dietary supplement containing a potent thyroid hormone. Tom was instrumental in getting the Phoenix to voluntarily hold the in-process batches of the product pending FDA's review of the matter. As a result of Tom's inspection, on 6/13, the district submitted a seizure recommendation to CDER. On 8/14, (don't know why it took so long) the recommendation was in the final stages of agency approval. I called Tom to inform him of the status and alert him of the need for an availability check. Tom went to Phoenix on 8/15, and succeeded in encouraging the firm to voluntarily destroy all of the in-process batches and labeling it had under voluntary hold. On 8/16, Tom witnessed the destruction and waste disposal of the articles and obtained a signed letter of voluntary destruction. I want to commend Tom for his inspectional skills and persuasiveness. By convincing the firm to voluntarily destroy the violative articles, Tom saved the agency much time and expense. But not only the agency. Tom obviated the need to involve the DOJ's Office of Consumer Litigation, the U.S. Attorney's Office, the U.S. Marshal's Office, and the U.S. District Court. Collectively, that's a lot of time and money Tom saved the taxpayer. More importantly, it resulted in the most efficient way of removing the violative articles from commerce and ultimately protecting the consumer. In my opinion, that's a good job that should be recognized.

Bruce