UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

Case No.: 09-12498
Hon. Arthur J. Tarnow
Magistrate Judge Donald A. Scheer

v.

All articles of drug, including active and inactive pharmaceutical components and in-process materials and components, in any size and type of container, labeled or unlabeled (excluding sealed containers of active and inactive pharmaceutical components and any finished drug product manufactured by Sun Pharmaceutical Industries, Ltd., which may be distinguished by lot numbers containing JK or GK in the initial digits), which are located anywhere on the premises of Caraco Pharmaceutical Laboratories, Ltd., 1150 Elijah McCoy Drive, Detroit, Michigan, 24700 Crestview Court, Farmington Hills, Michigan, and 31060 Oak Creek Drive, Wixom, Michigan, to which may be affixed labels bearing, among other things, the name and address of the manufacturer, packer, or distributor located outside the State of Michigan, or which are otherwise determined to consist of whole or in part of components that have originated outside the State of Michigan,

Defendants.
_____/

COMPLAINT FOR FORFEITURE OFADULTERATED ARTICLES OF DRUG

Now comes the United States of America by Terrence Berg, United States Attorney for the Eastern District of Michigan, and Julia Caroff Pidgeon, Assistant United States Attorney, and shows to the Court:

NATURE OF THE ACTION

1. This complaint is filed by the United States of America, and requests seizure and condemnation of articles of drug, as described in the caption, in accordance with the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. 301 et seq.

2. There are in the possession of Caraco Pharmaceutical Laboratories, Ltd., at 1150 Elijah McCoy Drive, Detroit, Michigan; 24700 Crestview Court, Farmington Hills, Michigan; and 31060 Oak Creek Drive, Wixom, Michigan, and/or elsewhere within the jurisdiction of this Court, articles of drug, which articles consist in whole or in part of one or more components that were shipped in interstate commerce from outside the State of Michigan.

JURISDICTION AND VENUE

3. The United States brings this action *in rem* to condemn and forfeit the defendant property. This Court has jurisdiction over an action commenced by the United States under 28 U.S.C. 1345 and 21 U.S.C. 334, which provides the court with jurisdiction over seizures brought under the Act.

4. That this Court has *in rem* jurisdiction over the articles because they are located in the Eastern District of Michigan. Upon filing of this complaint, the United States requests the Court issue an arrest warrant *in rem* pursuant to Supplemental Rule G(3)(b), which will be used to execute upon the articles pursuant to Supplemental Rule G(3).

BASIS FOR FORFEITURE

5. All of the articles of drug are adulterated while held for sale, after shipment of one or more of their components in interstate commerce, within the meaning of the Act, 21 U.S.C. 351(a)(2)(B), in that the methods used in, and the facilities and controls used for, their manufacture, processing, packing, and/or holding do not conform to and are not operated and

administered in conformity with current good manufacturing practice (GMP) requirements for drugs, 21 CFR Part 211. Thus, there is no assurance that the drugs meet the safety requirements of the Act and have the identity and strength, and meet the quality and purity characteristics, which they purport and are represented to possess.

6. By reason of the foregoing, the articles of drug are held illegally within the jurisdiction of this Court and are liable to seizure and condemnation.

FACTS

7. The Food and Drug Administration (FDA) issued a Warning Letter to Caraco on October 31, 2008, identifying numerous significant GMP (Good Manufacturing Practices) violations found during a May 1 - June 11, 2008, inspection. The letter requested that the violations be corrected and stated that failure to correct them may result in regulatory action, including seizure and/or injunction. In a November 24, 2008, letter to FDA, the firm stated that appropriate actions had been taken to correct the deficiencies.

8. A subsequent FDA inspection conducted on March 11 - May 12, 2009, revealed continuing significant GMP violations, including, but not limited to, the following:

(a) failure to follow written procedures for the storage and handling of components [21 CFR 211.80(a)], for example:

(i) the firm did not follow its standard operating procedure for raw material dispensing. Materials were placed in locations not properly recorded and the use of the material was undocumented. Such poor practices resulted in the loss of 1.352kg of digoxin drug substance which the firm, to date, has not been able to locate; and

(ii) material shortages and corrections found during the dispensing process have led to improper documentation and loss of material identity.

(b) failure to follow written procedures for the execution of the production and process control functions for "charge-in" of components to a batch [21 CFR 211.101(b) and (c)], for example:

(i) the firm allows materials to be shared between weighing rooms without appropriate verification before use and proper recording of the materials. Specifically, during the weighing process for paroxetine ready to compress granules, the wrong component (lactose of different grade) was borrowed from another weighing room and added to the batch being weighed. This error was detected when the empty drums were being removed from the room; and

(ii) a similar event happened in 2008 for two batches and was not detected by the firm until final product testing.

(c) failure to maintain accurate inventory records of each component and a reconciliation of the use of each lot of such component [21 CFR 211.184(c)], for example:

(i) FDA investigators found an investigation by the firm of 27 inventory discrepancies where materials could not be reconciled based upon the inventory records maintained by the firm.

(d) failure to have written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they are represented to possess [21 CFR 211.100(a)], for example:

(i) the firm manufactured tablet drug products before adequately evaluating processing issues.

(e) failure to establish and follow written procedures describing the in-process controls and tests, or examinations on uniformity and integrity of drug products [21 CFR 211.110(a)], for example:

(i) the firm relied on a visual examination of lots of tablets to remove any tablets that were thick or thin;

(ii) the in-process controls for these lots were not effective in identifying drug product with out-of-specification weight variation;

(iii) while reviewing batch record documentation, the FDA investigators found numerous instances where machine problems were identified and portions of the batches produced during these periods were not segregated or investigated. Many of these same lots were packaged and released by the firm and complaints or Adverse Drug Event Reports (ADEs) were received;

(iv) during investigation of the complaints, the firm analyzed samples of the lots. Some of the investigations confirmed that marketed product lots had weight variation outside of specification limits;

(v) the firm's own investigations revealed that the visual culling process was not effective;

(vi) the firm has not identified the root cause of its manufacturing/equipment problems; and

(vii) without correction of the flaws in production, such problems are likely to persist.

(f) failure of equipment used in the manufacture, processing, packing, or holding of a drug product to be of appropriate design to facilitate operations for its intended use [21 CFR 211.63], for example:

(i) Digoxin drug products have been recalled by the firm due to its inability to assure consistent quality; and

(ii) the firm has produced Digoxin tablets which have weight variations outside of the specifications.

(g) failure to conduct thorough investigations of any unexplained discrepancies and failures of batches to meet any of their specifications and failure to extend such investigations to other batches of the same drug product or other drug products that may have been associated with the specific failure or discrepancy [21 CFR 211.192], for example:

(i) the firm failed to timely investigate out of specification inventory reconciliations for 9 different drug substances and failed to investigate the root cause of these discrepancies; and

(ii) a customer complaint was received for Metoprolol tablets, 25 mg for observed thick tablets. The firm conducted an investigation and subsequently recalled the lot. The firm failed to extend this investigation to other lots of Metoprolol, although there were numerous other complaints for tablet weight variation (i.e., thick and thin tablets).

(h) failure to establish and follow written procedures applicable to the quality control unit [21 CFR 211.22(d)], for example:

(i) Quality Assurance allowed a change to the batch material weighing documentation which was not evaluated to determine effects of the change for all drugs that would use this new process. This change in the weighing process contributed to subsequent errors in processing during the manufacturing of a batch of Digoxin tablets; and

(ii) Quality Assurance allowed use of a different tablet press without adequate evaluation of its effect on the consistency of the tablet compression operation. Subsequently, the batches manufactured had serious problems during the compression stage. The tablets produced under these changes have exhibited weight variation outside established limits.

(i) failure of the firm to conduct follow-up to investigations of complaints [21 CFR 211.198(b)(2)], for example:

(i) the firm received a complaint for tablet size variation and an Adverse Drug Event (involving hospitalization) for a lot of Digoxin 0.125 mg tablets; and

(ii) there is no evidence that the retained tablets were properly evaluated to determine the potential impact of the thick or thin tablets and super-potency before the complaint was closed. A health hazard evaluation was also not performed for this investigation. Finally, the investigation was not extended to other lots of this same drug product.

9. In a June 19, 2009, letter to FDA, the firm stated that actions had been taken to correct the GMP violations identified during FDA's March 11 - May 12, 2009, inspection. The firm's June 19, 2009, letter revealed that significant GMP violations, identified during FDA's March 11

- May 12, 2009, inspection, continue. Further, the firm has not implemented some remedial actions identified in the letter.

We request that process issue against the articles; that all persons having any interest in the articles be cited to appear herein and answer the allegations in the complaint; that this Court decree the condemnation of the articles and grant the United States the costs of this proceeding against the claimant(s) of the articles; that the articles be disposed of as this Court may direct pursuant to the provisions of the Act; and that the United States have such other and further relief as may be appropriate.

TERRENCE BERG
United States Attorney

s/Julia Caroff Pidgeon
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Dated: June 24, 2009

VERIFICATION

I, Judith A. Putz, Compliance Officer for the Food and Drug Administration, U.S. Department of Health and Human Services, have read the foregoing Complaint for Forfeiture in this action and state that its contents are true and correct to the best of my knowledge, information, and belief.

Pursuant to 28 U.S.C. 1746, I declare under penalty of perjury that the foregoing is true and correct.

This 24th day of June, 2009.

Judith A. Putz
Compliance Officer
Food and Drug Administration

Complaints, Amended Complaints and Other Pleadings

2:09-cv-12498 United States of America v. Adulterated Articles of Drug

U.S. District Court

Eastern District of Michigan

Notice of Electronic Filing

The following transaction was entered by Pidgeon, Julia on 6/24/2009 at 2:40 PM EDT and filed on 6/24/2009

Case Name: United States of America v. Adulterated Articles of Drug
Case Number: 2:09-cv-12498
Filer: United States of America
Document Number: 1

Docket Text:
COMPLAINT *FOR FORFEITURE* filed by United States of America against Adulterated Articles of Drug. No summons requested. County of 1st Plaintiff: USA - County Where Action Arose: Wayne - County of 1st Defendant: Wayne. [Previously dismissed case: No] [Possible companion case(s): None] (Pidgeon, Julia)

2:09-cv-12498 Notice has been electronically mailed to:

Julia C. Pidgeon julia.pidgeon@usdoj.gov, patti.turczynski@usdoj.gov

2:09-cv-12498 Notice will not be electronically mailed to:

The following document(s) are associated with this transaction:

Document description: Main Document
Original filename:n/a
Electronic document Stamp:
[STAMP dcecfStamp_ID=1047317467 [Date=6/24/2009] [FileNumber=3188487-0] [c0c05a66ebab60cb0a7c8c2b10d60c99d088ab01398fe2a9b956e85c2842313298f a64beacdfeaeb65b40b31e8011bbb08eec315840cebc0dc9b669e4bd522ba]]