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Enforcement Report -- Edited Edition

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The FDA Enforcement Report is published weekly by the Food and Drug Administration, Department of Health and Human Services. It contains information on actions taken in connection with agency Regulatory activities.

May 11, 2005

05-19

RECALLS AND FIELD CORRECTIONS: DRUGS - CLASS II

PRODUCT

a) Armour Thyroid (thyroid tablets, USP), 30 mg.,
Rx only, packaged in 100 tablet bottle containers.
Product label contains NDC 0456-0458-01 (FOREST).
Recall # D-217-5;

b) Armour Thyroid (thyroid tablets, USP), 60 mg.,
Rx only, packaged in 100 tablet bottle containers.
Product label contains NDC 0456-0459-01 (FOREST).
Recall # D-218-5;

c) Armour Thyroid (thyroid tablets, USP), 120 mg.,
Rx only, packaged in 100 tablet bottle containers.
Product label contains NDC 0456-0461-01 (FOREST).
Recall # D-219-5.

CODE

a) Lots 034052, 035064, 035066, 036171, and 036456;
b) Lots 034053, 034488, 035065, 035997, 036500, 040423;
c) Lots 034051, 035067, 035995, 035996, 036499, 042018.

RECALLING FIRM/MANUFACTURER

Recalling Firm: Amerisource Health Services, Columbus, OH, by letter on April 12, 2005.
Manufacturer: Forest Pharmaceuticals, Inc., Earth City, MO. Firm initiated recall is ongoing.

REASON

Subpotent: Product may not maintain potency throughout shelf life.

VOLUME OF PRODUCT IN COMMERCE

58,544/100 tablet bottles.

DISTRIBUTION

Nationwide.

RECALLS AND FIELD CORRECTIONS: DRUGS - CLASS III

PRODUCT

a) Forest Armour Thyroid (thyroid tablets, USP), 1 $\frac{1}{4}$ Grain (15 mg),

- each tablet contains levothyroxine (T4) 9.5 mcg and liothyronine (T3) 2.25 mcg, packaged in 100-tablet bottles, RX, NDC 0456-0457-01. Recall # D-196-5;
- b) Forest Armour Thyroid (thyroid tablets, USP), 1/2 Grain (30 mg), each tablet contains levothyroxine (T4) 19 mcg and liothyronine (T3) 4.5 mcg, packaged in 100- and 1,000-tablet bottles, 10/10-tablet unit dose strips, and in 50,000-tablet drums for repacking only, RX, NDC 0456-0458-01, -00, -63, and ,69 respectively. Recall # D-197-5;
- c) Forest Armour Thyroid (thyroid tablets, USP), 1 Grain (60 mg), each tablet contains levothyroxine (T4) 38 mcg and liothyronine (T3) 9 mcg, packaged in 100-, 1,000-, and 5,000-tablet bottles, 10/10-tablet unit dose strips boxes, and 50,000-tablet drums for repacking only, RX, NDC 0456-0459-01, -00, -51, -63, and ,69 respectively. Recall # D-198-5;
- d) Forest Armour Thyroid (thyroid tablets, USP), 1 1/2 Grain (90 mg), each tablet contains levothyroxine (T4) 57 mcg and liothyronine (T3) 13.5 mcg, packaged in 100-tablet bottles, RX, NDC 0456-0460-01. Recall # D-199-5;
- e) Forest Armour Thyroid (thyroid tablets, USP), 2 Grain (120 mg), each tablet contains levothyroxine (T4) 76 mcg and liothyronine (T3) 18 mcg, packaged in 100- and 1,000-tablet bottles, 10/10-tablet unit dose strip boxes, and 50,000-tablet drums for repacking only, RX, NDC 0456-0461-01, -00, -63, and ,69 respectively. Recall # D-200-5;
- f) Forest Armour Thyroid (thyroid tablets, USP), 3 Grain (180 mg), each tablet contains levothyroxine (T4) 114 mcg and liothyronine (T3) 27 mcg, packaged in 100-tablet bottles, RX, NDC 0456-0462-01. Recall # D-201-5;
- g) Forest Armour Thyroid (thyroid tablets, USP), 4 Grain (240 mg), each tablet contains levothyroxine (T4) 152 mcg and liothyronine (T3) 36 mcg, packaged in 100-tablet bottles, RX, NDC 0456-0463-01. Recall # D-202-5;
- h) Forest Armour Thyroid (thyroid tablets, USP), 5 Grain (300 mg), each tablet contains levothyroxine (T4) 190 mcg and liothyronine (T3) 45 mcg, packaged in 100-tablet bottles, RX, NDC 0456-0464-01. Recall # D-203-5.

CODE

- a) Lot 080301, Exp. May-05; Lot 080302, Exp. May-05, and Lot 080303, Exp. May-05;
- b) Unit dose , Lot 100317, Exp. Aug-05;
100-tablet bottles , Lot 060325, Exp. May-05,
Lot 080304, Exp. Jun-05; Lot 080329, Exp. Jun-05;
Lot 090317, Exp. Aug-05; Lot 100317, Exp. Aug-05;
50,000-tablet drum , Lot 060324, Exp. May-05;
Lot 080304, Exp. Jun-05; Lot 090317, Exp. Aug-05;
1,000-tablet bottle , Lot 060324, Exp. May-05;
Lot 060325, Exp. May-05; Lot 100317, Exp. Aug-05;
- c) Unit dose , Lot 070322, Exp. Jun-05;
100-tablet bottles , Lot 070311, Exp. May-05,
Lot 070321, Exp. Jun-05; Lot 070322, Exp. Jun-05;
1,000-tablet bottles - Lot 090308, Exp. Aug-05;
50,000-tablet drums , Lot 070311, Exp. May-05;
Lot 110319, Exp. Aug-05;
- d) 100-tablet bottles , Lot 040355, Exp. Mar-05;
Lot 050315, Exp. Mar-05; Lot 080340, Exp. Jul-05;
Lot 100319, Exp. Aug-05;
- e) Unit dose , Lot 080330, Exp. Jul-05;
100-tablet bottles , Lot 040334, Exp. Mar-05,
Lot 040335, Exp. May-05; Lot 070306, Exp. May-05;

Lot 080330, Exp. Jul-05; Lot 100318, Exp. Aug-05;
50,000-tablet drum , Lot 040334, Exp. Mar-05,
Lot 070306, Exp. May-05, Lot 080330, Exp. Jul-05;
1,000-tablet bottles - Lot 040334, Exp. Mar-05;
Lot 040335, Exp. May-05.

f) Lot 050350, Exp. Apr-05; and Lot 080339, Exp. Jul-05;

g) Lot 040347, Exp. Mar-05;

h) Lot 040348, Exp. Mar-05.

RECALLING FIRM/MANUFACTURER

Recalling Firm: Forest Pharmaceuticals, Inc, Earth City, MO, by letters dated March 17, 2005 and March 31, 2005.

Manufacturer: Forest Pharmaceuticals, Inc, Cincinnati, OH. Firm initiated recall is ongoing.

REASON

Stability failures.

VOLUME OF PRODUCT IN COMMERCE

6,891/10/10-tab. unit dose strip boxes;

598,552/100-tab. bottles;

10,984/1,000-tab. bottles;

350/5,000-tab. bottles;

441/50,000-tab. drums.

DISTRIBUTION

Nationwide and Internationally.

PRODUCT

a) Armour Thyroid (thyroid tablets, USP), 1/2 Grain (30 mg), each tablet contains levothyroxine (T4) 19 mcg and liothyronine (T3) 4.5 mcg, packaged in 100-tablet bottles, Rx, NDC 0456-0458-01. Recall # D-214-5;

b) Armour Thyroid (thyroid tablets, USP), 1 Grain (60 mg), each tablet contains levothyroxine (T4) 38 mcg and liothyronine (T3) 9 mcg, packaged in 100-tablet bottles, Rx, NDC 0456-0459-01. Recall # D-215-5.

CODE

a) Lot Nos.: 09164, 09330, 09792, 10427, 10918, 11215;

b) Lot Nos.: 09530, 09531, 09787, 10011, 10794, 11540, 11541.

RECALLING FIRM

Rx PAK, Memphis, TN, by intranet on March 23, 2005. Firm initiated recall is complete.

REASON

Stability Failure.

VOLUME OF PRODUCT IN COMMERCE

135,500 units.

DISTRIBUTION

Nationwide.

END OF ENFORCEMENT REPORT FOR May 11, 2005

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