

LABEL IN PART: (Drum) "Del-Caps 15 Timed Disintegration Capsule * * * Each capsule contains 15 mg. of Dextro-Amphetamine Sulfate in a special base that provides for the disintegration of the contents throughout a period of 6-10 hours * * * 3259" and "Del-Bardex #2 Timed Disintegration Capsule Each Capsule Contains Dextro-Amphetamine Sulfate 15 Mg. Amobarbital 100 Mg. * * * Each capsule contains 15 Mg. of Dextro-Amphetamine Sulfate * * * in a special base that provides for the disintegration of the contents throughout a period of about 6-10 hours * * * 3100."

RESULTS OF INVESTIGATION: The capsules in the btls. had been repacked from the above-mentioned drums by the consignee after shipment.

Analysis showed that the *Del-Caps capsules* released 94 percent of their dextro-amphetamine sulfate content in 2 hours and that the *Del-Bardex capsules* released 80 percent of their dextro-amphetamine sulfate content in 2 hours.

LIBELED: 2-17-58, E. Dist. Pa.

CHARGE: 501(c)—the quality of the articles, when shipped, differed from that which they purported or were represented to possess in that they failed to disintegrate at a uniform rate over a 6- to 10-hour period; and 502(a)—the labels contained false and misleading representations that the dextro-amphetamine sulfate content of the articles would be released at a uniform rate over a 6- to 10-hour period.

DISPOSITION: 3-27-58. Default—destruction.

5596. Del-Bardex capsules. (F.D.C. No. 41491. S. No. 29-803 P.)

QUANTITY: 4 drums containing a total of 98,000 capsules at Jersey City, N.J.

SHIPPED: 12-17-57, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

LABEL IN PART: "Del-Bardex # 2 Timed Disintegration Capsule Each Capsule Contains: Dextro-Amphetamine Sulphate 15 Mg. Amobarbital 100 Mg. * * * disintegration * * * period of about 6-10 hours."

RESULTS OF INVESTIGATION: Analysis showed that 90 percent of the dextro-amphetamine sulfate content of the article was released in 2 hours.

LIBELED: 3-28-58, Dist. N.J.

CHARGE: 501(c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess since it failed to disintegrate at a uniform rate over a 6- to 10-hour period; and 502(a)—the label statement "disintegration * * * period of about 6-10 hours" was false and misleading.

DISPOSITION: 4-28-58. Default—destruction.

5597. S.C. red pyrilamine maleate tablets. (F.D.C. No. 40995. S. No. 80-326 M.)

QUANTITY: 1 case containing 10,000 tablets at Minneapolis, Minn.

SHIPPED: 8-29-57, from St. Louis, Mo.

RESULTS OF INVESTIGATION: Examination showed that the article had a strong odor of acetic acid, contained large cracks in its coating due to bursting, and contained a significant amount of free salicylic acid.

LIBELED: 11-22-57, Dist. Minn.

CHARGE: 501(c)—the quality of the article, while held for sale, fell below that which it purported and was represented to possess since the tablet coatings were bursting and the aspirin was decomposing.

DISPOSITION: 1-6-58. Default—destruction.