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Burnside et al.

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(54) **ORAL PULSED DOSE DRUG DELIVERY SYSTEM**

(75) Inventors: **Beth A. Burnside**, Bethesda; **Xiaodi Guo**, Derwood; **Kimberly Fiske**, Bethesda; **Richard A. Couch**, Chevy Chase; **Donald J. Treacy**, Annapolis, all of MD (US); **Rong-Kun Chang**, Hockessin, DE (US); **Charlotte McGuinness**, Bethesda; **Edward M. Rudnic**, North Potomac, both of MD (US)

(73) Assignee: **Shire Laboratories, Inc.**, Rockville, MD (US)

(*) Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(51) **Int. Cl.⁷** **A61K 9/16**

(52) **U.S. Cl.** **424/494; 424/472; 424/480**

(58) **Field of Search** 424/494, 457, 424/471, 472, 480, 497, 461, 462, 470, 458, 459, 460, 468, 482

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Primary Examiner—Diana Dudash

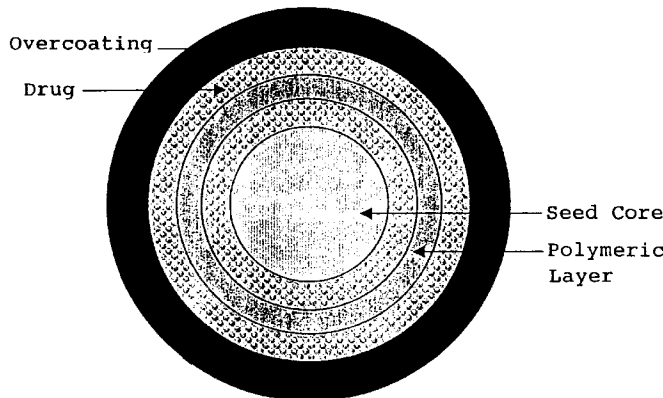
Assistant Examiner—Alysia Berman

(74) *Attorney, Agent, or Firm*—Elliot M. Olstein; Raymond J. Lillie

(57) **ABSTRACT**

A multiple pulsed dose drug delivery system for pharmaceutically active amphetamine salts, comprising an immediate-release component and an enteric delayed-release component wherein (1) the enteric release coating has a defined minimum thickness and/or (2) there is a protective layer between the pharmaceutically active amphetamine salt and the enteric release coating and/or (3) there is a protective layer over the enteric release coating. The product can be composed of either one or a number of beads in a dosage form, including either capsule, tablet, or sachet method for administering the beads.

24 Claims, 8 Drawing Sheets



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FIG. 1

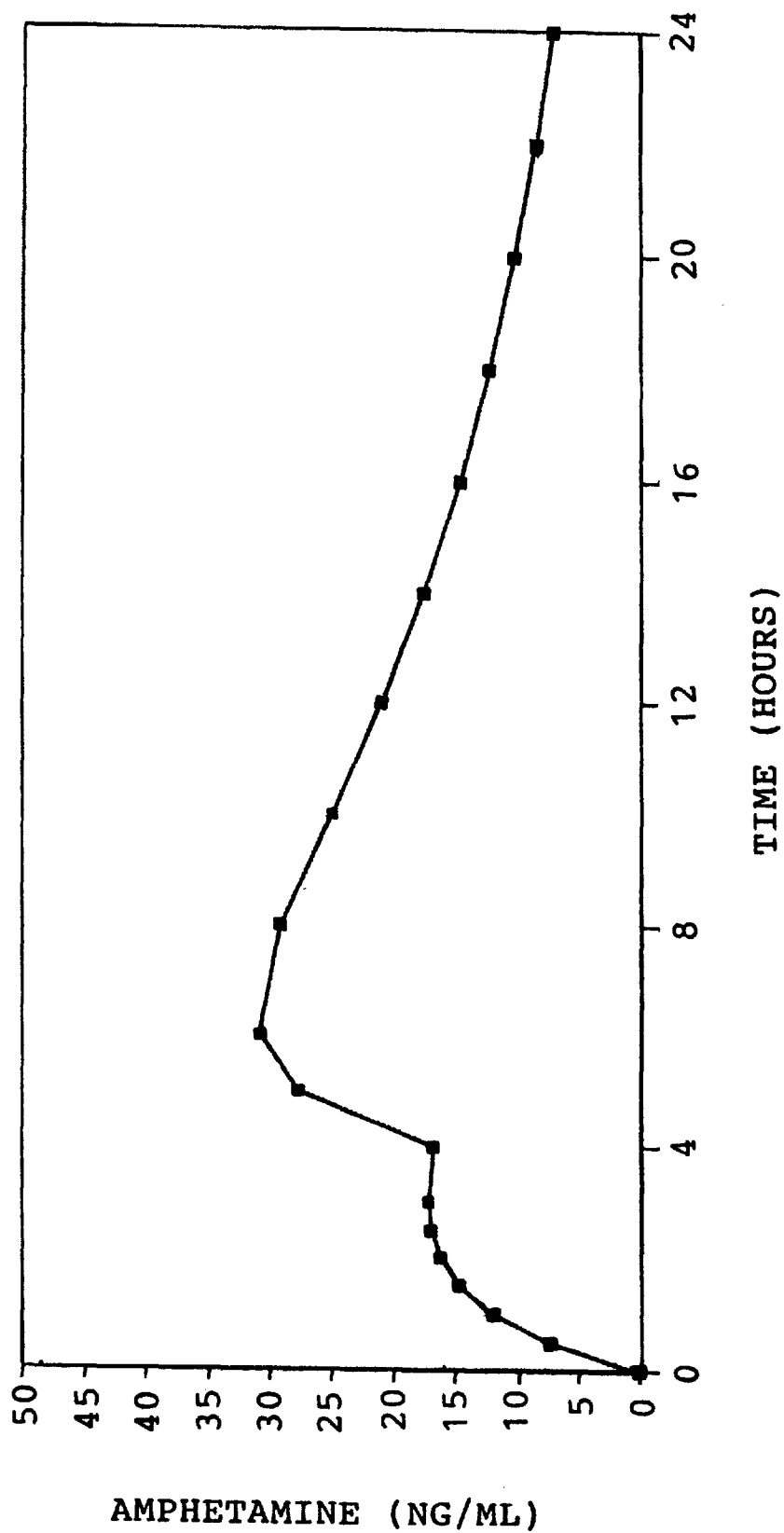


FIG. 2A

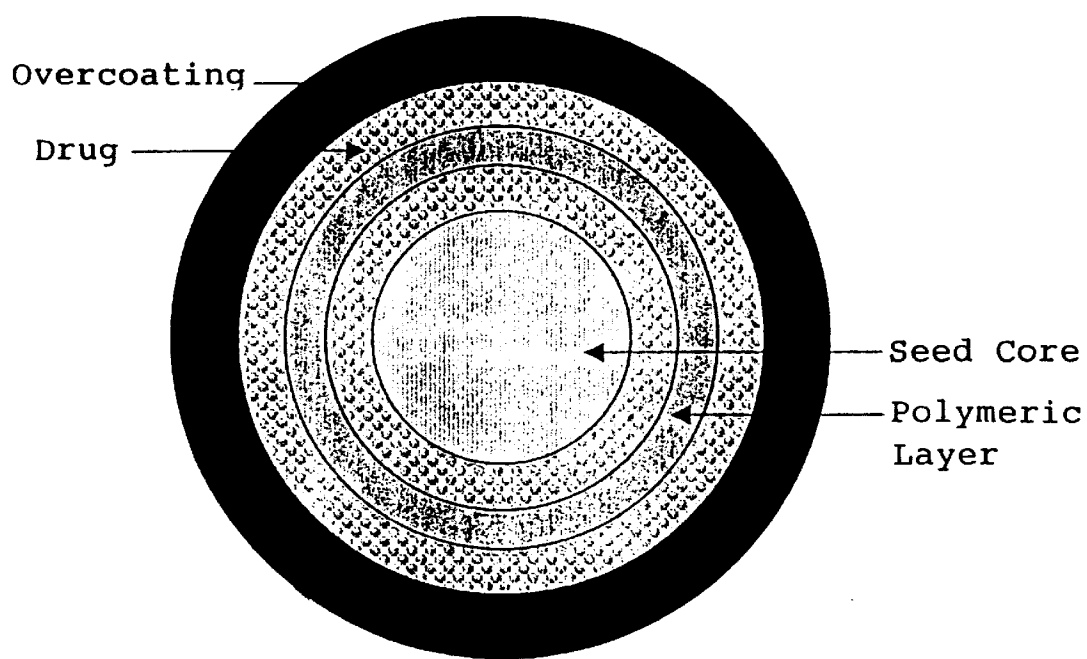
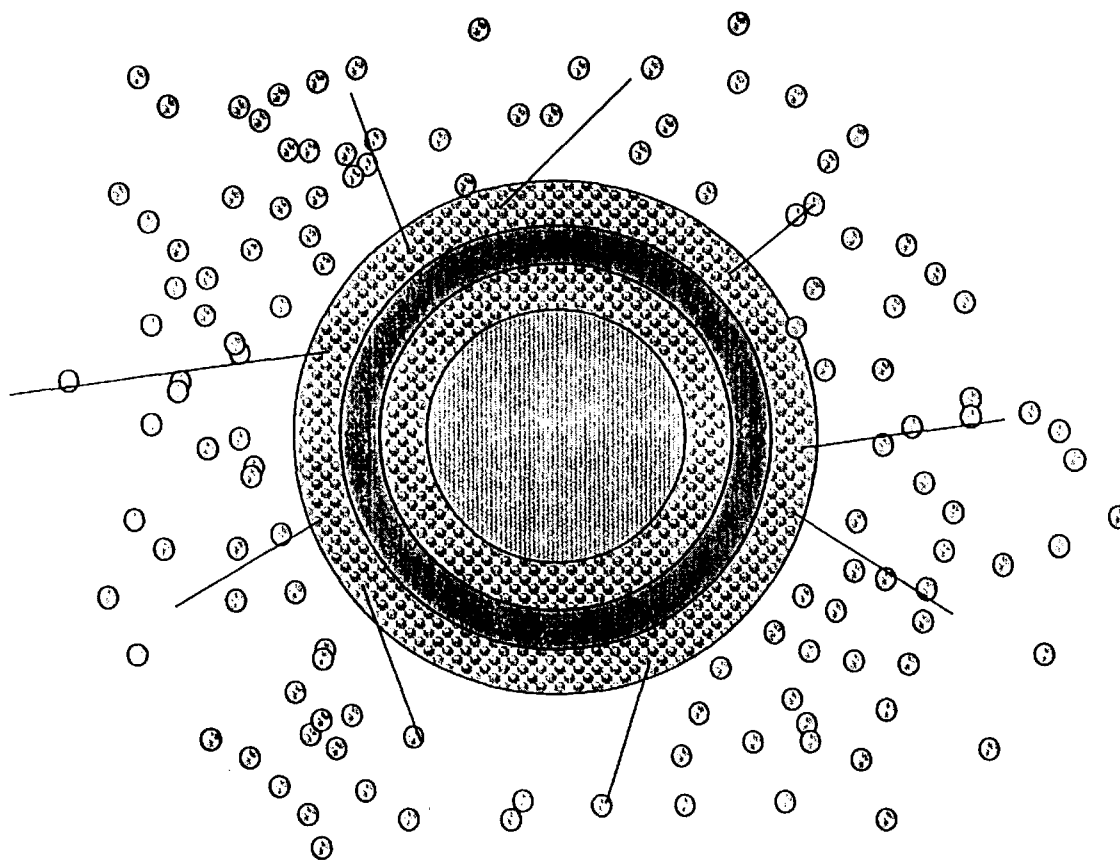


FIG. 2B



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