Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

[PART 768—AMENDED]

■ 23. The authority citation for 15 CFR part 768 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

[PART 770—AMENDED]

■ 24. The authority citation for 15 CFR part 770 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

[PART 772—AMENDED]

■ 25. The authority citation for 15 CFR part 772 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

[PART 774—AMENDED]

■ 26. The authority citation for 15 CFR part 774 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.*, 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 46 U.S.C. app. 466c; 50 U.S.C. app. 5; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

Dated: November 26, 2007.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. E7–23249 Filed 11–29–07; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310 and 369

[Docket No. 1976N–0052T (formerly Docket No. 76N–052T)]

RIN 0910–AF33

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Final Rule for Over-the-Counter Antitussive Drug Products; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations (exemption for certain drugs limited by new-drug applications to prescription sale, and warning and caution statements required by regulations for drugs) by removing the entries for carbetapentane citrate. This action is associated with FDA's determination that carbetapentane citrate has not been shown to be effective at the over-the-counter (OTC) doses stated in the exempting regulation. FDA made this determination in 1987 as part of its ongoing review of OTC drug products.

DATES: This rule is effective November 30, 2007.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5496, Silver Spring, MD 20993, 301–796–2090.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 13, 1957 (22 FR 7315), FDA proposed to exempt carbetapentane citrate preparations from the prescription-dispensing requirements of section 503(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the act) (formerly 21 U.S.C. 353(b)(1)(C); currently 21 U.S.C. 353(b)(1)(B)). FDA stated:

- Evidence now available through investigation and marketing experience shows that drug products containing this ingredient can be safely used by the laity in self-medication if they are used in accordance with the proposed labeling and
- The restriction to prescription sale is no longer necessary for the protection of the public health.

FDA did not receive any comments on this proposal and published a final order (final rule) in the **Federal Register** of November 1, 1957 (22 FR 8812). FDA amended § 130.102 (21 CFR 130.102) by adding new paragraph (a)(20) with marketing conditions for OTC drug products containing carbetapentane citrate labeled for the temporary relief of cough. FDA subsequently recodified § 130.102(a)(20) as § 310.201(a)(20) (21 CFR 310.201(a)(20)).

As part of FDA's OTC drug review, the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (the Panel) evaluated carbetapentane citrate and found it safe but lacking adequate effectiveness data for OTC antitussive use (41 FR 38312 at 38345, September 9, 1976). In the tentative final monograph for OTC antitussive drug products (48 FR 48576 at 48580, October 19, 1983), one comment objected to the Panel's effectiveness determination. FDA responded that it agreed with the Panel's conclusions that the data were insufficient to establish effectiveness. FDA did not receive any additional effectiveness data on carbetapentane citrate. In the final rule for OTC antitussive drug products (52 FR 30042, August 12, 1987), FDA classified carbetapentane citrate as nonmonograph (not generally recognized as safe and effective) for OTC antitussive use.

II. The Technical Amendment

Because carbetapentane citrate had not been shown to be effective at the OTC dosages stated in § 310.201(a)(20), FDA should have removed that paragraph from § 310.201 in 1987. The current final rule corrects that oversight by removing paragraph (a)(20) from § 310.201 and reserving paragraph (a)(20) for future use. In addition, the entry for ''CARBETAPENTANE CITRATE PREPARATIONS'' in § 369.21 (21 CFR 369.21) states: ''(See Cough-Due-to-Cold Preparations.)'' The entry for '''COUGH-DUE-TO-COLD' PREPARATIONS'' entry states: ''(CARBETAPENTANE CITRATE). (See § 310.201(a)(20) of this chapter.) 'Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.''' Both of those entries also should have been removed in 1987, and the current final rule removes them.

III. Analysis of Impacts

FDA has examined the impacts of this final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et*

seq.). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity).

Under the Regulatory Flexibility Act, if a rule has a significant economic impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure in any 1 year by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation).

FDA has determined that this final rule is consistent with the principles set out in Executive Order 12866 and in these two statutes. The final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order. As explained later in this document, the final rule will not have a significant economic impact on a substantial number of small entities. The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for this final rule, because the rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation. The current inflation adjusted statutory threshold is about $127 million using the most current (2006) Implicit Price Deflator for the Gross Domestic Product.

The purpose of this final rule is to remove the exemption in § 310.201(a)(20) for carbetapentane citrate from the prescription-dispensing requirements of section 503(b)(1)(B) of the act and to remove two entries for carbetapentane citrate in § 369.21. FDA has reviewed its Drug Listing System and determined that there currently are no marketed OTC drug products that contain carbetapentane citrate. Therefore, FDA certifies that this final rule will not have a significant economic impact on a substantial number of small entities. No further analysis is required under the Regulatory Flexibility Act (5 U.S.C. 605(b)).

IV. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Environmental Impact

FDA has determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that this rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Any effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government occurred in 1987 when FDA classified carbetapentane citrate as not generally recognized as safe and effective for OTC antitussive use. States had the opportunity to comment at the time that final rule was published (52 FR 30042, August 12, 1987). Accordingly, FDA has concluded that this rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

List of Subjects

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 369

Labeling, Medical devices, Over-the-counter drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 310 and 369 are amended as follows:

PART 310—NEW DRUGS

■ 1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

§ 310.201 [Amended]

■ 2. In § 310.201 remove and reserve paragraph (a)(20).

PART 369—INTERPRETATIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE

■ 3. The authority citation for 21 CFR part 369 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 371.

§ 369.21 [Amended]

■ 4. In § 369.21 remove the following entries:

''CARBETAPENTANE CITRATE PREPARATIONS. (See Cough-Due-to-Cold Preparations.)''

'''COUGH-DUE-TO-COLD'PREPARATIONS (CARBETAPENTANE CITRATE). (See § 310.201(a)(20) of this chapter.) 'Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.'''

Dated: November 26, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–23207 Filed 11–29–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 864

[Docket No. 2005N–0017]

Medical Devices; Hematology and Pathology Devices: Reclassification of Automated Blood Cell Separator Device Operating by Centrifugal Separation Principle

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying from class III to class II the automated blood cell separator device operating by centrifugal separation principle and intended for the routine collection of blood and blood components. FDA is taking this action on its own initiative based on new information. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document that will serve as the special controls for this device, as well as the special controls for the device with the same intended use but operating on a filtration separation principle.