Corrective Actions for Certain Airplanes

(i) For Model MD–90–30 airplanes and Model 717–200 airplanes: If any crack is found in the door jamb or jamb structure of a lower cargo door during any inspection required by paragraph (g)(1) or (g)(2) of this AD, and the service bulletin specifies contacting Boeing for appropriate action, before further flight, repair the crack using a method in accordance with paragraph (o) of this AD.

Corrective Actions for Certain Other Airplanes

(j) For Model DC–9–11, DC–9–12, DC–9–13, DC–9–14, DC–9–15, DC–9–15F, DC–9–21, DC–9–31, DC–9–32, DC–9–32 (VC–9C), DC–9–32F, DC–9–33F, DC–9–34, DC–9–34F, DC–9–32F (C–9A, C–9B), DC–9–41, DC–9–51 airplanes; Model DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), and DC–9–87 (MD–87) airplanes; and Model MD–88 airplanes: If any crack is found during any inspection required by paragraph (g)(1), (g)(2), or (h) of this AD, do the corrective action at the applicable compliance time specified in paragraph 1.E. of the service bulletin, in accordance with the Accomplishment Instructions of the service bulletin, as applicable.

Optional Replacement of Stop Pad Support Fittings

(k) For all airplanes: Replacement of all early configuration stop pad support fittings installed on a lower cargo door with new configuration or new stop pad support fittings, as identified in the applicable service bulletin; and reidentification of the applicable lower cargo door; in accordance with the Accomplishment Instructions of the applicable service bulletin; terminates the repetitive inspections required by paragraphs (g)(1), (g)(2), and (h) of this AD, as applicable, for that lower cargo door only.

Parts Installation

(l) For all airplanes: As of the effective date of this AD, no person may install an early configuration stop pad support fitting having P/N 3925046–1, –501, –505, –507, or –509, or P/N 3926046–1 or –501, on any airplane.

Credit for Previous Service Bulletin

(m) Actions done before the effective date of this AD in accordance with Boeing Service Bulletin DC9–52–189, dated August 10, 2001, are acceptable for compliance with the corresponding requirements of this AD.

Terminating Action for Certain Requirements of AD 96–10–11

(n) For Model DC–9–11, DC–9–12, DC–9–13, DC–9–14, DC–9–15, DC–9–15F, DC–9–21, DC–9–31, DC–9–32, DC–9–32 (VC–9C), DC–9–32F, DC–9–33F, DC–9–34, DC–9–34F, DC–9–32F (C–9A, C–9B), DC–9–41, and DC–9–51 airplanes: Accomplishing the replacement specified in paragraph (k) of this AD for the forward and aft lower cargo doors terminates the repetitive inspections of the forward and aft lower cargo doors for cracks required by paragraph (b) of AD 96–10–11 as specified in McDonnell Douglas DC–9 Service Bulletin 52–89, Revision 5, dated February 26, 1991.

Alternative Methods of Compliance (AMOCs)

(o)(1) The Manager, Los Angeles Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by an Authorized Representative for the Boeing Commercial Airplanes Delegation Option Authorization Organization who has been authorized by the Manager, Los Angeles ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane and 14 CFR 25.571, Amendment 45, and the approval must specifically refer to this AD.

Issued in Renton, Washington, on August 24, 2005.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–17402 Filed 8–31–05; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. 2005N–0345]

RIN 0910–AF72

Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking to request comment on whether to initiate a rulemaking to codify its interpretation of section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301, *et seq.*), regarding when an active ingredient may be simultaneously marketed in both a prescription drug product and an over-the-counter (OTC) drug product.

DATES: Submit written or electronic comments by November 1, 2005.

ADDRESSES: You may submit comments, identified by Docket No. 2005N–0345 and/or RIN number 0910–AF72, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: For further information contact the FDA at 301–827–0002 or by e-mail at *pcomments@fda.gov*. This phone number and this e-mail account have been set-up to address questions relating to this notice.

SUPPLEMENTARY INFORMATION:

I. Background

Since Congress first enacted the Federal Food, Drug, and Cosmetic act (the act) in 1938, there has been a great deal of discussion about when drug products should be sold as prescription drugs as opposed to OTC drugs.

Until 1951, the act did not contain criteria for determining when to limit a drug's approval to prescription use. Consequently, different manufacturers made different decisions about whether to market a drug as prescription or OTC. This resulted in confusion and uncertainty for pharmacists and consumers, and made it difficult for FDA to ensure that the only drugs available OTC were those that were safe for use without the supervision of a licensed medical practitioner.

To eliminate this confusion and uncertainty, and to protect the public health, Congress enacted the Durham-Humphrey Amendments in 1951 (Public Law 82–215, 65 Stat. 648). Congress had two primary objectives in enacting the Amendments: (1) To protect the public from abuses in the sale of potent Rx drugs; and (2) to relieve retail pharmacists and the public from burdensome and unnecessary restrictions on the dispensing of drugs that are safe for use without the supervision of a physician. See S. Rep. No. 946, at 1 (1951), reprinted in 1951 U.S.C.C.A.N. 2454. To this end, the new legislation codified a statutory definition of prescription drug in section 503(b) of the act.

Section 503(b) of the act sets forth the Federal standard used to classify drugs as prescription or OTC, and it describes when and how to switch a drug from prescription to OTC status. Section 503(b)(1) of the act defines a prescription drug as:

(1) A drug intended for use by man which—

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(B) is limited by an approved application under section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug.

The act does not define ''OTC drug,'' but the term has been adopted to refer to any drug that does not meet the definition of prescription drug in section 503(b) of the act.

Given this dichotomy between prescription and OTC drugs, questions have arisen over the years about whether there are any conditions under which an active ingredient may be simultaneously marketed in both a prescription drug product and an OTC drug product. FDA has interpreted the language in 503(b)(1) of the act to allow marketing of the same active ingredient in products that are both prescription and OTC, assuming some meaningful difference exists between the two that makes the prescription product safe only under the supervision of a licensed practitioner. Examples of such drugs include: Meclizine (prescription for vertigo/OTC for nausea with motion sickness); Clotrimazol (prescription for candidiasis/OTC for athlete's foot, ring worm, jock itch); Loperamide (prescription for chronic diarrhea/OTC for acute diarrhea); Nicotine products (prescription for administration through inhalers and nasal sprays/OTC in gums, lozenges and patches); ibuprofren (prescription at 400mg+ for arthritis/OTC at 400mg and below for aches and pains); and H2 blockers (prescription at 300mg+ for ulcers/OTC at 200mg for heartburn). The key distinction in these examples is that there is some meaningful difference between the two products (e.g., indication, strength, route of administration, dosage form) that makes the prescription product safe only under the supervision of a licensed practitioner. To date, FDA has not allowed marketing of the same active ingredient in a prescription product for one population and in an OTC product for a subpopulation.

II. Agency Request for Information

Despite the preceding examples, we recognize that FDA's interpretation of section 503(b) of the act has not been explicitly set forth in any of the regulations that discuss the process by which FDA classifies (or re-classifies) drugs as OTC or prescription. See, e.g., 21 CFR 310.200 and 310.201.

To address this concern, we therefore ask for comments on the following questions:

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

C. If so, would a rulemaking on this issue help dispel that confusion?

2.

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

B. If it could, would it be able to do so as practical matter and, if so, how?

3.

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m. Monday through Friday.

Dated: August 26, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–17390 Filed 8–26–05; 4:59 pm]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–102144–04]

RIN 1545–BD10

Dual Consolidated Loss Regulations; Hearing Cancellation

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Cancellation of notice of public hearing on proposed rulemaking.

SUMMARY: This document cancels a public hearing on proposed regulations under section 1503(d) of the Internal Revenue Code (Code) regarding dual consolidated losses.

DATES: The public hearing originally scheduled for September 7, 2005, at 10 a.m., is cancelled.

FOR FURTHER INFORMATION CONTACT: Robin R. Jones of the Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration) at (202) 622–7180 (not a toll-free number).

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking and notice of public hearing that appeared in the **Federal Register** on Tuesday, May 24, 2005 (70 FR 29868) announced that a public hearing was scheduled for September 7, 2005, at 10 a.m., in the IRS Auditorium, Internal Revenue Service