DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. 76N–052N]

RIN 0910–AA01

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; OTC Nasal Decongestant Drug Products; Partial Stay of Final Rule; Enforcement Policy

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; partial stay of regulation; enforcement policy.

SUMMARY: The Food and Drug Administration (FDA) is staying part of a final rule that established that certain over-the-counter (OTC) nasal decongestant drug products are not generally recognized as safe and effective and are misbranded. This action is being taken in response to a citizen petition for a stay of enforcement action initiated or initially introduced or initially delivered for introduction into interstate commerce unless it complies with appropriate standards that are included in the USP, the nasal decongestant active ingredient were new drugs under section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)). The effective date of the final rule was August 23, 1995. To be marketed, OTC topical nasal decongestant drug products containing l-desoxyephedrine would require an application or abbreviated application approved under section 505 of the act (21 U.S.C. 355) and part 314 (21 CFR part 314). In the absence of an approved application, OTC topical nasal decongestant drug products containing l-desoxyephedrine would be misbranded under section 502 of the act (21 U.S.C. 352). The agency also stated that should interested parties develop appropriate standards that are included in the USP, the nasal decongestant final monograph would be amended to include the ingredient and § 310.545(a)(6)(ii)(B) will be revised accordingly.

During the stay period, the following labeling requirements will be in effect for topical nasal decongestant drug products containing l-desoxyephedrine:

1. The statement of identity should follow § 310.545(a)(6)(ii)(B) of the final monograph for OTC nasal decongestant drug products (59 FR 43386 at 43409).
2. The indications should follow § 341.80(b) of the final monograph for OTC nasal decongestant drug products (59 FR 43386 at 43409 and 43410).
3. The warnings should follow § 341.80(c)(2)(i) of the final monograph for OTC nasal decongestant drug products (59 FR 43386 at 43410).

4. The directions are for a product that must deliver 0.04 to 0.150 milligram of l-desoxyephedrine in each 800 milliliters of air. Adults and children 12 years of age and over: Two inhalations in each nostril not more often than every 2 hours. Children 6 to 12 years of age (with adult supervision): One inhalation in each nostril not more often than every 2 hours. Children under 6 years of age: Consult a doctor.

5. Other required statements should follow § 341.80(d)(viii)(A) and (d)(viii)(B).

As part of the conditions of this stay of action, the agency has determined that manufacturers of OTC nasal decongestant drug products containing l-desoxyephedrine should implement this labeling within 6 months of the publication of this partial stay.

Therefore, on or after September 9, 1995, no OTC drug product containing l-desoxyephedrine may be initially introduced or initially delivered for introduction into interstate commerce unless its labeling conforms to the conditions of this partial stay.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–105), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2304.

SUPPLEMENTAL INFORMATION:

I. Background

In the Federal Register of August 23, 1994 (59 FR 43386), the agency published a final rule in the form of a final monograph establishing conditions under which OTC nasal decongestant drug products are generally recognized as safe and effective. The final monograph did not include l-desoxyephedrine as a nasal decongestant active ingredient. The final rule listed l-desoxyephedrine in § 310.545(a)(6)(ii)(B) (21 CFR 310.545(a)(6)(ii)(B)) as not generally recognized as safe and effective. L-desoxyephedrine was declared nonmonograph because it was not currently standardized and characterized for quality and purity in an official compendium, i.e., the United States Pharmacopeia (USP)/National Formulary (NF) (59 FR 43386 at 43408). The agency stated in the final rule that OTC drug products containing l-desoxyephedrine as a topical nasal decongestant active ingredient were new drugs under section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)). The effective date of the final rule was August 23, 1995. To be marketed, OTC topical nasal decongestant drug products containing l-desoxyephedrine would require an application or abbreviated application approved under section 505 of the act (21 U.S.C. 355) and part 314 (21 CFR part 314). In the absence of an approved application, OTC topical nasal decongestant drug products containing l-desoxyephedrine would be misbranded under section 502 of the act (21 U.S.C. 352). The agency also stated that should interested parties develop appropriate standards that are included in the USP, the nasal decongestant final monograph would be amended to include the ingredient and § 310.545(a)(6)(ii)(B) will be revised accordingly.

Therefore, on or after September 9, 1996, no OTC drug product containing l-desoxyephedrine may be initially introduced or initially delivered for introduction into interstate commerce unless it complies with appropriate standards that are included in the USP, the nasal decongestant active ingredient were new drugs under section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)). The effective date of the final rule was August 23, 1995. To be marketed, OTC topical nasal decongestant drug products containing l-desoxyephedrine would require an application or abbreviated application approved under section 505 of the act (21 U.S.C. 355) and part 314 (21 CFR part 314). In the absence of an approved application, OTC topical nasal decongestant drug products containing l-desoxyephedrine would be misbranded under section 502 of the act (21 U.S.C. 352). The agency also stated that should interested parties develop appropriate standards that are included in the USP, the nasal decongestant final monograph would be amended to include the ingredient and § 310.545(a)(6)(ii)(B) will be revised accordingly.

Therefore, on or after September 9, 1995, no OTC drug product containing l-desoxyephedrine may be initially introduced or initially delivered for introduction into interstate commerce unless its labeling conforms to the conditions of this partial stay.
1996, no OTC drug product that is subject to this partial stay of the final rule for OTC nasal decongestant drug products may be initially introduced or initially delivered for introduction into interstate commerce unless its labeling conforms to the conditions of this partial stay. Further, any OTC drug product subject to this partial stay that is repackaged or relabeled after the date of publication of this partial stay must be in compliance with the partial stay regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with this partial stay at the earliest possible date.

This partial stay of action applies only to l-desoxyephedrine in OTC topical nasal decongestant drug products and not to any other nasal decongestant active ingredient included under § 310.545(a)(6)(ii)(B).

II. References

The following references are on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

(1) Comment No. CP1, Docket No. 95P-0245, Dockets Management Branch.
(2) Draft Compendial Monograph, in Comment No. CP1, Docket No. 95P-0245, Dockets Management Branch.
(3) Memorandum of telephone conversation between M. T. Benson, FDA, and T. Cecil, United States Pharmacopeial Convention, Inc., coded as MT1, Docket No. 95P-0245, Dockets Management Branch.
(4) Letter from W. E. Gilbertson, FDA, to S. Rexinger, Leiner Health Products, and E. Lambert, Covington & Burling, coded as LET1, Docket No. 95P-0245, Dockets Management Branch.

III. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements discussed in this document are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Rather, the labeling statements are a "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

List of Subjects in 21 CFR Part 310

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

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 310 is amended as follows:

PART 310—NEW DRUGS

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


§ 310.545 [Partial stay]

2. In § 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses in paragraph (a)(6)(ii)(B), the entry for "l-desoxyephedrine (topical)" is stayed until further notice.


William K. Hubbard, Associate Commissioner for Policy Coordination.
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