

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 of regulatory action against OTC nasal decongestant drug products containing the active ingredient l-desoxyephedrine. The agency is also providing labeling requirements for OTC topical nasal decongestant drug products containing l-desoxyephedrine. This action is part of the ongoing review of OTC drug products conducted by FDA.

DATES: This partial stay is effective August 31, 1995. 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 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.

SUPPLEMENTARY 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 l-desoxyephedrine as a topical nasal decongestant active ingredient. The agency reserved 21 CFR 341.20(b)(1) of the final monograph for OTC nasal decongestant drug products for possible future inclusion of l-desoxyephedrine as a topical nasal decongestant active ingredient.

Subsequently, a citizen petition (Ref. 1) requested that the agency defer the effective date of § 310.545(a)(6)(ii)(B) as it applies to l-desoxyephedrine (topical) until December 31, 1996. The petitioner stated that it had forwarded a draft compendial monograph (Ref. 2) for l-desoxyephedrine to the USP in late July 1995. The petition stated that USP expects to publish a proposed monograph for public comment in the November/December 1995 issue of *Pharmacopeial Forum*, and expects the resulting monograph to become official with publication of USP23/NF18 Supplement No. 5, on November 15, 1996. The petition stated that USP, as a practical matter, will have concluded to adopt the monograph for l-desoxyephedrine well before November 15, 1996, and will have given notice of that conclusion in its *Pharmacopeial Forum* Interim Revision Announcement. The petitioner stated its belief that the agency should have ample time to initiate its process to amend the nasal

decongestant final monograph by the end of 1996.

The agency was subsequently informed that the ingredient might become official in the USP in November 1996 or May 1997 (Ref. 3). On August 31, 1995, the agency stated its intent to stay the effective date for l-desoxyephedrine in the list of active ingredients in § 310.545(a)(6)(ii)(B) until December 31, 1996, to permit time for USP processing to include the ingredient in a compendial monograph (Ref. 4). At this time, the agency is staying the entry for "l-desoxyephedrine (topical)" in § 310.545(a)(6)(ii)(B) until further notice. When l-desoxyephedrine becomes official in the USP, the final monograph for OTC nasal decongestant drug products will 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 § 341.80(a) (21 CFR 341.80(a)) 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). In addition, the following warnings are required: "Do not use this product for more than 7 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, consult a doctor."

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 under 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 topical 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,

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:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512-516, 520, 601(a), 701, 704, 705, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b-360f, 360j, 361(a), 371, 374, 375, 379e); secs. 215, 301, 302(a), 351, 354-360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b-263n).

§ 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.

Dated: February 22, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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