

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section/ FDA Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Average Hours per Response	Total Operating & Maintenance Costs	Total Hours
CAPs						
70.25	0	1	0	0	0	0
71.1	2	1	2	1,652	\$5,600	3,304
FDA Form 3504	1	1	1	1	0	1
GRAS Af- firmation Petitions						
170.35	1	1	1	2,598		2,598
FAPs						
171.1	7	1	7	3,640		25,480
FDA Form 3503	2	1	2	1		2
Total					\$5,600	31,385

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of burden for FAPs and CAPs is based on the average number of new FAPs and CAPs received in calendar years 2000 through 2002 and the total hours expended in preparing the petitions. Although the burden varies with the type of petition submitted, an average FAP or CAP, or GRAS affirmation petition, involves analytical work and appropriate toxicological studies, as well as the work of drafting the petition itself. The burden varies depending on the complexity of the petition, including the amount and types of data needed for scientific analysis.

Electronic submissions of petitions contain the same petition information required for paper submission. The agency estimates that up to 30 percent of the petitioners for both food and color additives will take advantage of the electronic submission process. By using the guidelines and forms that FDA is providing, the petitioner will be able to organize the petition to focus on the information needed for FDA's safety review. Therefore, we estimate that petitioners will only need to spend approximately 1 hour completing the

electronic submission application form (Form 3503 or 3504, as appropriate) because they will have already used the guidelines to organize the petition information needed for the submission.

The labeling requirements for food and color additives were designed to specify the minimum information needed for labeling in order that food and color manufacturers may comply with all applicable provisions of the act and other specific labeling acts administered by FDA. Label information does not require any additional information gathering beyond what is already required to assure conformance with all specifications and limitations in any given food or color additive regulation. Label information does not have any specific recordkeeping requirements unique to preparing the label. Therefore, because labeling requirements under § 70.25 for a particular color additive involve information required as part of the CAP safety review process, the estimate for number of respondents is the same for § 70.25 and § 71.1, and the burden hours for labeling are included in the estimate for § 71.1. Also, because labeling

requirements under parts 172, 173, 175 through 178, and 180 for particular food additives involve information required as part of the FAP safety review process under § 171.1, the burden hours for labeling are included in the estimate for § 171.1.

Dated: March 31, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 02P-0057]

#### Determination That Albuterol Sulfate Inhalation Solution 0.5% Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined that albuterol sulfate inhalation solution 0.5% (Ventolin) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for albuterol sulfate inhalation solution 0.5%.

**FOR FURTHER INFORMATION CONTACT:**

Mary E. Catchings, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products with Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)). FDA may not approve an ANDA that does not refer to a listed drug.

Albuterol sulfate inhalation solution 0.5% is the subject of NDA 19-269 held by GlaxoSmithKline. Albuterol sulfate inhalation solution 0.5% is indicated for

the relief of bronchospasm in patients with reversible obstructive airway disease and acute attacks of bronchospasm.

On February 1, 2002, Nephron Pharmaceuticals Corp. submitted a citizen petition (Docket No. 02P-0057) under 21 CFR 10.30 to FDA requesting that the agency determine whether albuterol sulfate inhalation solution 0.5% was withdrawn from sale for reasons of safety or effectiveness. The agency has determined that albuterol sulfate inhalation solution 0.5% was not withdrawn for reasons of safety or effectiveness. In support of that finding, we note that GlaxoSmithKline notified the agency in July 2001 that albuterol sulfate inhalation solution 0.5% was being withdrawn from sale because of a decline in sales. FDA has independently evaluated relevant literature and data for adverse event reports and has found no information that would indicate that this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing its records, FDA determines that, for reasons outlined previously, albuterol sulfate inhalation solution 0.5% was not withdrawn for reasons of safety or effectiveness. Accordingly, the agency will continue to list albuterol sulfate inhalation solution 0.5% in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued for reasons other than safety or effectiveness. ANDAs that refer to albuterol sulfate inhalation solution 0.5% may be approved by the agency.

Dated: March 28, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 03D-0118]

#### Guidance for FDA Staff on Sampling or Detention Without Physical Examination of Decorative Contact Lenses (Import Alert #86-10); Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the

availability of a guidance document entitled "Guidance for FDA Staff on Sampling or Detention Without Physical Examination of Decorative Contact Lenses (Import Alert #86-10)." The guidance document includes FDA's guidance to FDA district offices for sampling or detention without physical examination of plano (zero-powered or noncorrective) contact lenses intended solely to change the appearance of the normal eye in decorative fashion, when these products are presented for importation into the United States.

**DATES:** Submit written or electronic comments on the guidance by June 3, 2003.

**ADDRESSES:** Submit written requests for single copies of the Import Alert #86-10, to the Division of Import Operations and Policy (HFC-170), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request. You may fax your request to 301-594-0413. Submit written comments on this guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Thaddeus J. Poplawski, Division of Import Operations and Policy (HFC-170), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6553.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA has been receiving reports that certain commercial entities are planning to distribute or may already be distributing plano (zero-powered or noncorrective) contact lenses intended solely to change the normal appearance of the eye in decorative fashion (decorative contact lenses). FDA understands that these products are intended to be distributed without a prescription, without fitting by a qualified eye care professional, and without ongoing professional supervision.

FDA believes that, like other contact lenses, decorative contact lenses can cause a variety of eye injuries and conditions. Lens wear has been associated with corneal ulcer, for example, which can progress rapidly, leading to internal ocular infection if left untreated. Uncontrolled infection