

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02P-0057]

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**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Withdrawn From Sale for Reasons of Safety or Effectiveness**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Food and Drug Administration (FDA) has determined that albuterol sulfate inhalation solution 0.5% (Ventolin) was not withdrawn from sale for reasons of safety or effectiveness.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 Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

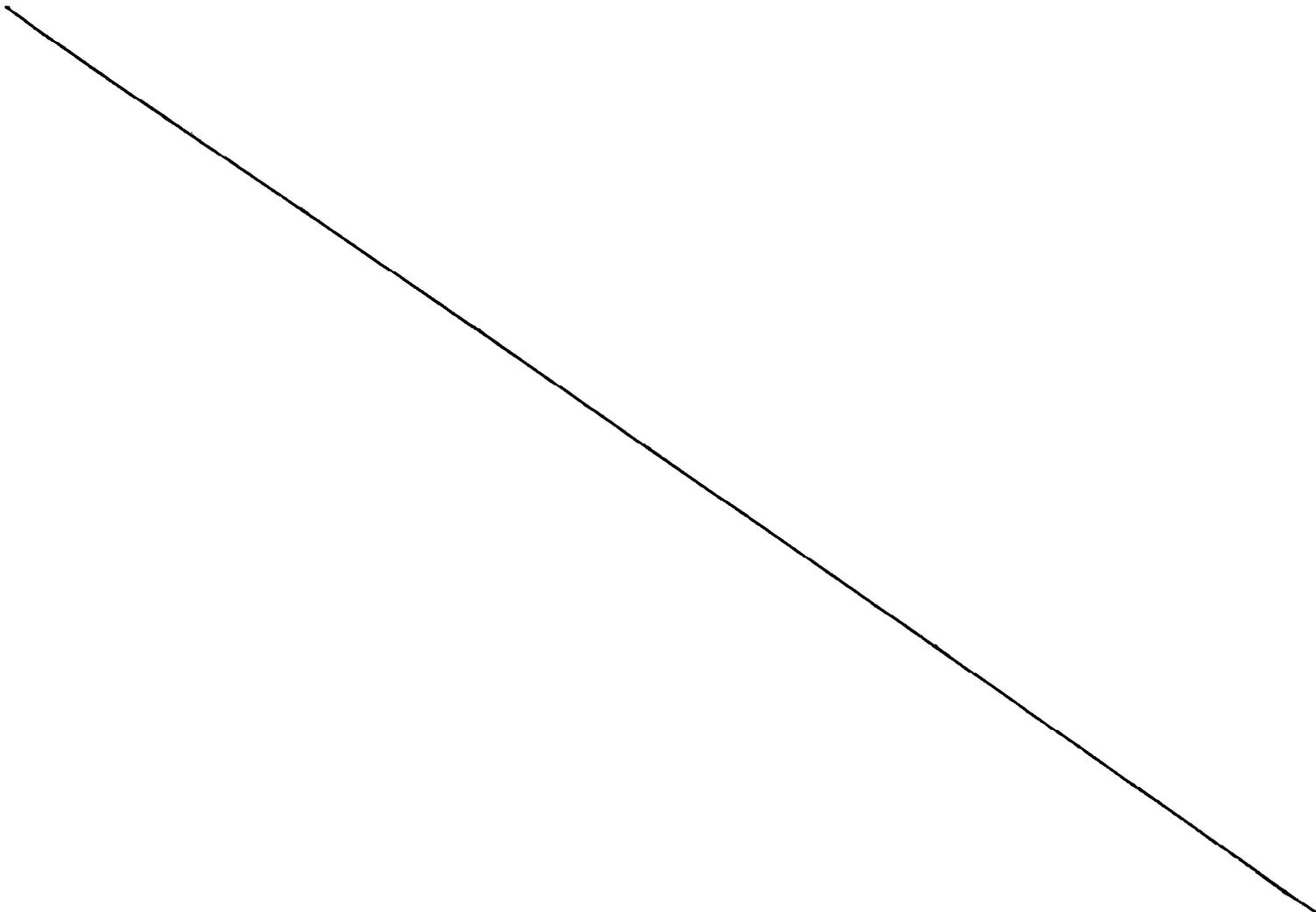
Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)). FDA may not approve an ANDA that does not refer to a listed 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: 3/28/03
March 28, 2003.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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