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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

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Certifier A. Corbin

[Docket No. 2004P-0051]

**Determination That DYCLONE (Dyclonine Hydrochloride) 0.5% and 1.0%  
Topical Solutions Were Not Withdrawn From Sale for Reasons of Safety or  
Effectiveness**

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

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) has determined that DYCLONE (dyclonine hydrochloride (HCl)) 0.5% and 1.0% Topical Solutions were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for DYCLONE HCl 0.5 and 1.0% Topical Solutions.

**FOR FURTHER INFORMATION CONTACT:** Mary 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. Sponsors of ANDAs do not have to repeat the extensive clinical

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testing otherwise necessary to gain approval of a new drug application (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 removed 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of the drug’s NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under 21 CFR 314.161(a)(1), the agency must determine 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. FDA may not approve an ANDA that does not refer to a listed drug.

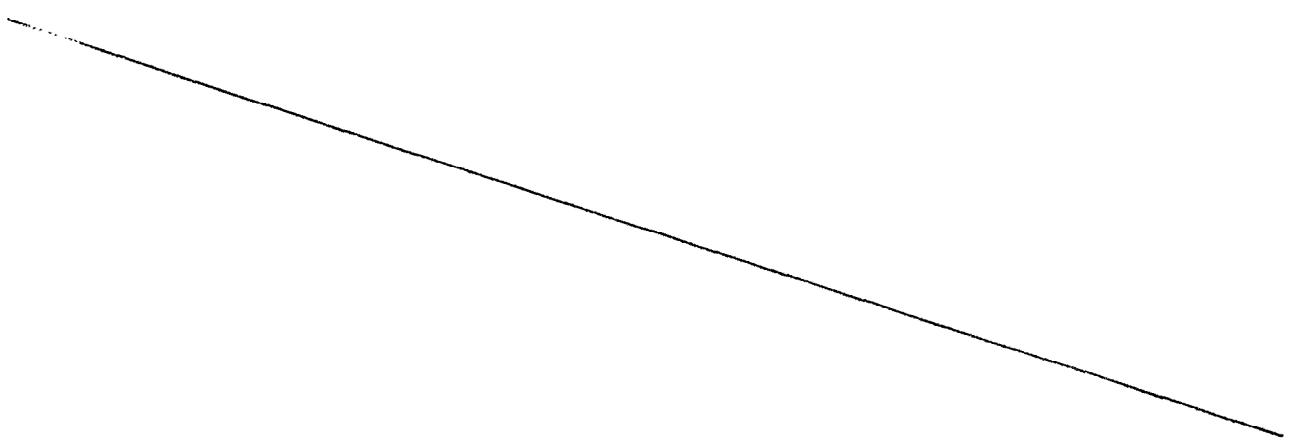
DYCLONE (dyclonine HCl) 0.5% and 1.0% Topical Solutions were the subject of approved NDA 9–925 held by AstraZeneca LP. DYCLONE Topical Solutions were labeled for anesthetizing accessible mucus membranes prior to various endoscopic procedures. DYCLONE 0.5% Topical Solution was also labeled to block the gag reflex, to relieve the pain of oral ulcers or stomatitis, and to relieve pain associated with ano-genital lesions.

In a citizen petition dated February 3, 2004 (Docket No. 2004P–0051/CP1), submitted under 21 CFR 10.25(a) and 10.30, Arent Fox, PLLC, requested that the agency determine whether DYCLONE (dyclonine HCl) 0.5% and 1.0% Topical Solutions were withdrawn from the market for reasons of safety or

effectiveness. In the **Federal Register** of February 11, 2002 (67 FR 6264), FDA withdrew approval of NDA 9–925 for DYCLONE 0.5% and 1.0% Topical Solutions after AstraZeneca notified the agency that DYCLONE was no longer being marketed under NDA 9–925 and requested withdrawal of that application.

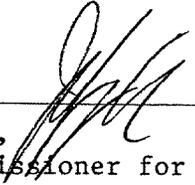
The agency has determined that DYCLONE 0.5% and 1.0% Topical Solutions were not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that DYCLONE was withdrawn from sale as a result of safety or effectiveness concerns. FDA has independently evaluated relevant literature and data for adverse event reports and has found no information that would indicate that these products were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing agency records, FDA determines that, for the reasons outlined in this notice, dyclonine HCl 0.5% and 1.0% topical solutions approved under NDA 9–925 were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list DYCLONE (dyclonine HCl) 0.5% and 1.0% Topical Solutions 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 from marketing for reasons other than safety or effectiveness. ANDAs that refer to DYCLONE (dyclonine HCl) 0.5% and 1.0% Topical Solutions may be approved by the agency.

Dated: 11/8/04  
November 8, 2004.

  
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Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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