

Clindamycin Hydrochloride Capsules in dogs.

Both Delmarva Laboratories' CLINTABS Tablets and Phoenix Scientific's Clindamycin Hydrochloride Capsules are approved for the treatment of soft tissue infections (wounds and abscesses), dental infections, and osteomyelitis caused by susceptible strains of *Staphylococcus aureus*, soft tissue infections (deep wounds and abscesses), dental infections, and osteomyelitis caused by or associated with susceptible strains of *Bacteroides fragilis*, *Bacteroides melaninogenicus*, *Fusobacterium necrophorum*, and *Clostridium perfringens* as generic copies of Pharmacia & Upjohn's ANTIROBE Capsules, approved under NADA 120-161. The necessary amendments adding these sponsors' drug label codes to 21 CFR 520.446 were made in a final rule (67 FR 54954, August 27, 2002) for the approval of an unrelated supplemental NADA for the pioneer product.

Freedom of information summaries containing approved product labeling may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 25, 2003.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003N-0232]

#### Universal Reagents, Inc.; Opportunity for Hearing on a Proposal to Revoke U.S. License No. 0887

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for hearing on a proposal to revoke the biologics license (U.S. License No. 0887) issued to Universal Reagents, Inc. (URI), for the manufacture of Source Plasma. The proposed revocation is based on the failure of the establishment and the product for which the license has been issued to conform to the applicable standards established in the license and in the regulations.

**DATES:** URI may submit a written or electronic request for a hearing to the Division of Dockets Management by August 11, 2003, and any data and information justifying a hearing by September 8, 2003. Other interested persons may submit written or electronic comments on the proposed revocation to the Division of Dockets Management by September 8, 2003.

**ADDRESSES:** Submit written requests for a hearing, any data and information justifying a hearing, and any written comments on the proposed revocation to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic requests or comments to <http://www.fda.gov/dockets/ecomments>.

#### FOR FURTHER INFORMATION CONTACT:

Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:** FDA is initiating proceedings to revoke the biologics license (U.S. License No. 0887) issued to URI, 2858 North Pennsylvania St., Indianapolis, IN 46202, for the manufacture of Source Plasma. The proposed revocation is based on the failure of URI to conform to the applicable standards established in its license and certain requirements of subchapter F, parts 600 to 640 (21 CFR parts 600 to 640).

#### I. Findings

FDA inspected URI between May 29 and June 3, 2002. Additionally, on June 7, 2002, FDA inspected Central Indiana Regional Blood Center, Inc. (CIRBC), Indianapolis, IN, which performs infectious disease testing for URI under a contract agreement. FDA determined, through its investigation and inspections of both URI and CIRBC, that URI had significant deviations from the standards established in its license as well as in the applicable Federal regulations. FDA also documented that URI has willfully engaged in violative recordkeeping practices and falsified records it submitted to FDA. The deviations noted during the inspections included, but were not limited to, the following:

1. In violation of §§ 610.40(a) and 606.160(b)(2)(i), test results for Source Plasma units 0730900, 0730911, and 0730912 for the hepatitis B surface antigen (HBsAg) and the antibody to the human immunodeficiency virus types 1 and 2 (anti-HIV-1/2) were missing from the Transfer PC Mainframe Unit Rejection Report (a computer generated

report). On June 3, 2002, URI provided the FDA investigator with what URI identified as the missing test results. According to these results, the HBsAg and anti-HIV-1/2 tests, which purportedly were performed by CIRBC, were negative for Source Plasma units 0730900, 0730911, and 0730912. However, the document did not bear a date or time in the designated reporting fields. Contrary to the documents obtained at the URI inspection, FDA's inspection of CIRBC disclosed that the required testing for HBsAg and anti-HIV-1/2 was not completed or performed for these Source Plasma units.

2. In violation of §§ 610.40(a) and 606.160(b)(2)(i), HBsAg and anti-HIV-1/2 test results for Source Plasma unit 0729859 were missing on a Transfer Report and on a Testing Status Report. An additional notation on the Testing Status Report stated "sample too old to complete testing." An additional record that FDA collected during the URI inspection, a Laboratory Request Form dated June 4, 2001, that URI generated, showed that all test results for unit 0729859, including HBsAg and anti-HIV-1/2 testing, were documented as "NR" or nonreactive. During the closeout discussion on June 3, 2002, URI provided the FDA investigator with a Testing Status Report stating that the testing had been performed at CIRBC and that test results for HBsAg and anti-HIV-1/2 were "N" or negative for unit 0729859. Contrary to the documents obtained at the URI inspection, FDA's inspection of CIRBC disclosed that infectious disease testing for HBsAg and anti-HIV-1/2 was not performed on Source Plasma unit 0729859.

3. In violation of § 606.160(b)(2)(i), URI failed to maintain anti-HIV-1/2 re-testing results for Source Plasma unit 0729718. On a Transfer Report dated May 5, 2001, Source Plasma unit 0729718 tested reactive for anti-HIV-1/2 in testing conducted by CIRBC. Rather than producing the results of re-testing on that unit, however, URI provided the FDA investigator, during the closeout discussion on June 3, 2002, with a Testing Status Report for unit 0729718 that noted an "N" or "nonreactive" test result for the initial anti-HIV-1/2 test. No date or time was documented on the report; however, a notation on the report stated that it was reviewed by URI on May 9, 2000 [sic]. The sequence number noted on the report was 7899. FDA's inspection of CIRBC disclosed that all infectious disease testing related to anti-HIV-1/2 that CIRBC performed on unit 0729718 in 2001 was associated with sequence number 1995, not 7899. CIRBC's records showed that anti-HIV-