



ANDA 203978

ANDA APPROVAL

Interchem Corporation
U.S. Agent for InfoRLife SA
120 Route 17 North
Paramus, NJ 07652
Attention: Jeanne Squeglia
Vice President, Technical

Dear Jeanne Squeglia:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on June 20, 2013, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Nicardipine Hydrochloride in 0.83% Sodium Chloride Injection, 40 mg/200 mL (0.2 mg/mL), Single-Dose Containers and Nicardipine Hydrochloride in 0.86% Sodium Chloride Injection, 20 mg/200 mL (0.1 mg/mL), Single-Dose Containers.

Your product is a combination product as defined by 21 CFR 3.2(e) and is comprised of drug and device constituent parts.

Reference is also made to the complete response letter issued by this office on October 10, 2023, and to any amendments thereafter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C Act. Accordingly the ANDA is **approved**, effective on the date of this letter. We have determined your Nicardipine Hydrochloride in 0.83% Sodium Chloride Injection, 40 mg/200 mL (0.2 mg/mL), Single-Dose Containers, and Nicardipine Hydrochloride in 0.86% Sodium Chloride Injection, 20 mg/200 mL (0.1 mg/mL), Single-Dose Containers to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Cardene I.V. Injection, 40 mg/200 mL (0.2 mg/mL) and 20 mg/200 mL (0.1 mg/mL) of Chiesi USA Inc., (Chiesi).

The RLD upon which you have based your ANDA, Chiesi's Cardene I.V. Injection, 40 mg/200 mL (0.2 mg/mL) and 20 mg/200 mL (0.1 mg/mL), is subject to periods of patent protection. The following patents and expiration dates are currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
7,612,102 (the '102 patent)	December 26, 2027
7,659,291 (the '291 patent)	April 18, 2027
8,455,524 (the '524 patent)	April 18, 2027
9,364,564 (the '564 patent)	December 26, 2027
10,758,616 (the '616 patent)	April 18, 2027
11,547,758 (the '758 patent)	April 18, 2027

Your ANDA contains paragraph IV certifications to each of the patents¹, under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Nicardipine Hydrochloride in 0.83% Sodium Chloride Injection, 40 mg/200 mL (0.2 mg/mL), Single-Dose Containers, and Nicardipine Hydrochloride in 0.86% Sodium Chloride Injection, 20 mg/200 mL (0.1 mg/mL), Single-Dose Containers, under this ANDA. You have notified the Agency that InfoRLife SA (InfoRLife) complied with the requirements of section 505(j)(2)(B) of the FD&C Act. Litigation was initiated within the statutory 45-day period against InfoRLife for infringement of the '102 and '291 patents in the United States District Court for the District of New Jersey [Chiesi USA, Inc., Cornerstone BioPharma, Inc. and EKR Therapeutics, LLC v. Sandoz Inc., Sandoz AG and ACS Dobfar Info SA, Civil Action No. 13-05723]. You have also notified the Agency that this case was dismissed.

With respect to 180-day generic drug exclusivity, we note that InfoRLife was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Nicardipine Hydrochloride in 0.83% Sodium Chloride Injection, 40 mg/200 mL (0.2 mg/mL), Single-Dose Containers, and Nicardipine Hydrochloride in 0.86% Sodium Chloride Injection, 20 mg/200 mL (0.1 mg/mL), Single-Dose Containers. Therefore, with this approval, InfoRLife may be eligible for 180 days of generic drug exclusivity for Nicardipine Hydrochloride in 0.83% Sodium Chloride Injection, 40 mg/200 mL (0.2 mg/mL), Single-Dose Containers, and Nicardipine Hydrochloride in 0.86% Sodium Chloride Injection, 20 mg/200 mL (0.1 mg/mL), Single-Dose Containers. The Agency notes that InfoRLife failed to obtain tentative approval of its ANDA within 30 months after the date on which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) of the FD&C Act (forfeiture of exclusivity for failure to obtain tentative approval). The Agency is not, however, making a formal determination at this time of InfoRLife's eligibility for 180-day generic drug exclusivity. We will do so only if a subsequent paragraph IV applicant becomes eligible for full approval (a) within 180 days after InfoRLife's begins commercial marketing of Nicardipine Hydrochloride in 0.83% Sodium Chloride Injection, 40 mg/200 mL (0.2 mg/mL), Single-Dose Containers, and Nicardipine Hydrochloride in 0.86% Sodium Chloride Injection, 20 mg/200 mL (0.1 mg/mL),

Single-Dose Containers, or (b) at any time prior to the expiration of the '102 and '291 patents if InfoRLife's has not begun commercial marketing. Please submit correspondence to this ANDA notifying the Agency within 30 days of the date of the first commercial marketing of this drug product or the RLD. If you do not notify the Agency within 30 days, the date of first commercial marketing will be deemed to be the date of the drug product's approval. See 21 CFR 314.107(c)(2).

Please note that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ANDA referencing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standard for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website as <https://www.uspnf.com/>.

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas>.

Sincerely yours,

{See appended electronic signature page}

For Edward M. Sherwood
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

¹ The Agency notes that the '524, '564, '616 and '758 patents were submitted to the Agency after submission of your ANDA. Litigation, if any, with respect to these patents would not create a statutory stay of approval.



Paul
Levine

Digitally signed by Paul Levine

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