



ANDA 205307

**ANDA APPROVAL**

Watson Laboratories, Inc.  
400 Interpace Parkway  
Morris Corporate Center III  
Parsippany, NJ 07054  
Attention: Joyce Anne DelGaudio  
Executive Director, Regulatory Affairs

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated February 28, 2013, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for Propofol Injectable Emulsion USP, 200 mg/20 mL (10 mg/mL), 500 mg/50 mL (10 mg/mL), and 1,000 mg/100 mL (10 mg/mL) single-dose vials.

Reference is made to our complete response letter of March 31, 2015. Reference is also made to your amendments dated May 15, and July 8, 2015. The May 15, 2015 submission constituted a complete response to our March 31, 2015, action letter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. **Accordingly the ANDA is approved**, effective on the date of this letter. The Office of Bioequivalence has determined your Propofol Injectable Emulsion USP, 200 mg/20 mL (10 mg/mL), 500 mg/50 mL (10 mg/mL), and 1,000 mg/100 mL (10 mg/mL) single-dose vials, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Diprivan, Injectable Emulsion, 10 mg/mL, of Fresenius Kabi USA (Fresenius).

The RLD upon which you have based your ANDA, Fresenius' Diprivan Injectable Emulsion, 10 mg/mL, is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 8,476,010 (the '010 patent) is scheduled to expire on June 1, 2025 (with pediatric exclusivity added).

Your ANDA contains a paragraph IV certification to the '010 patent under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Propofol Injectable Emulsion USP, 200 mg/20 mL (10 mg/mL), 500 mg/50 mL (10 mg/mL), and 1,000 mg/100 mL (10 mg/mL) single-dose vials. You have notified the agency that Watson Laboratories, Inc. (Watson) complied with the requirements of section 505(j)(2)(B) of the FD&C Act. The agency notes that the '010 patent was submitted to the agency after submission of your ANDA and therefore, litigation, if any, with respect to this patent creates no statutory stay of approval.

With respect to 180-day generic drug exclusivity, we note that Watson was the first ANDA applicant for Propofol Injectable Emulsion USP, 200 mg/20 mL (10 mg/mL), 500 mg/50 mL (10 mg/mL), and 1,000 mg/100 mL (10 mg/mL), single-dose vials, to submit a substantially complete ANDA with a paragraph IV certification to the '010 patent. Therefore, with this approval, Watson is eligible for 180 days of generic drug exclusivity for Propofol Injectable Emulsion USP, 200 mg/20 mL (10 mg/mL), 500 mg/50 mL (10 mg/mL), and 1,000 mg/100 mL (10 mg/mL), single-dose vials. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, will begin to run from the earlier of the commercial marketing or court decision dates identified in section 505(j)(5)(B)(iv).<sup>1</sup> Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

Under section 506A of the FD&C Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

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

Post marketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Prescription Drug Promotion  
5901-B Ammendale Road  
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-

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<sup>1</sup> Because another ANDA for Propofol Injectable Emulsion USP, 200 mg/20 mL (10 mg/mL), 500 mg/50 mL (10 mg/mL), and 1,000 mg/100 mL (10 mg/mL), was submitted before December 8, 2003, the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173), this reference to the 180-day exclusivity provisions is to the section of the FD&C Act as in effect prior to December 8, 2003. See MMA § 1102(b)(1).

identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

Carol A. Holquist, RPh  
Acting Deputy Director  
Office of Regulatory Operations  
Office of Generic Drugs  
Center for Drug Evaluation and Research