DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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Stephen A. Campbell, Esq.
Senior Vice President, Regulatory Affairs
Amphastar Pharmaceuticals, Inc.
11570 6th Street
Rancho Cucamonga, CA 91730

Re: Docket No. FDA-2006-P-0134

Dear Mr. Campbell:

This letter responds to your citizen petition (Petition) dated February 28, 2006.[1] The Petition requests that the Food and Drug Administration (FDA or Agency) make a determination that the following propofol injectable emulsion products manufactured by AstraZeneca Pharmaceuticals (AstraZeneca), Teva Sicor (Teva), and Bedford Laboratories (Bedford) are misbranded under the Federal Food, Drug, and Cosmetic Act (the Act):

- AstraZeneca's Diprivan (new drug application (NDA) 019627)[2]
- Teva's Propofol Injectable Emulsion (abbreviated new drug application (ANDA) 075392)[3]
- Bedford's Propofol Injectable Emulsion (ANDA 074848)[4]

You assert that the above products are misbranded in that the immediate drug product container label and case label for each product state, "Contains no preservative" (Petition at 1). You also assert that Bedford's Propofol Injectable Emulsion is misbranded in that the company's Web page for the product includes the statement "Preservative Free" in multiple locations (Petition at 1).

Specifically, you state that Diprivan contains disodium edetate (0.005%) as a preservative "to retard the rate of growth of microorganisms" (Petition at 1). Similarly, you state that

[1] The Petition was originally assigned docket number 2006P-0092/CP1. The number was changed to FDA-2006-P-0134 as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008.

[2] According to the Agency's database of approved drug products, Drugs@FDA, the current sponsor for NDA 019627 is APP Pharmaceuticals, Inc.

[3] Teva's Propofol Injectable Emulsion has been discontinued and is currently listed in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

[4] Bedford's Propofol Injectable Emulsion has been discontinued and is currently listed in the "Discontinued Drug Product List" section of the Orange Book.

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Propofol Injectable Emulsion manufactured by Teva and marketed by Baxter Pharmaceutical Products, Inc., contains sodium metabisulfite (0.25 milligram/milliliter (mg/mL)) as a preservative with the same stated purpose: "to retard the growth of microorganisms" (Petition at 2). You also state that Bedford's Propofol Injectable Emulsion contains benzyl alcohol (1 mg/mL) as a preservative with the same stated purpose of "retard[ing] the growth of microorganisms" (Petition at 2). You assert that each of these products is misbranded under the Act because the labeling for each product contains statements indicating that it "Contains no preservative" or is "Preservative Free," which you assert renders the labeling "false or misleading in their particulars" (Petition at 5).

Under section 502 of the Act (21 U.S.C. 352), a drug is misbranded if, among other things, its labeling is "false or misleading in any particular" or its label or labeling does not contain certain required elements enumerated in the Act.[5] Under section 301(a) and (g) of the Act (21 U.S.C. 331(a) and (g)), the misbranding of a drug that is introduced or delivered for introduction into interstate commerce or the manufacture of any drug that is misbranded is prohibited.[6]

Under the Act, the Agency has the authority to, among other things, take certain enforcement actions if a drug product's labeling causes it to be misbranded. Under section 302 of the Act (21 U.S.C. 332), the United States district courts and the United States courts of the Territories have jurisdiction, for cause shown, to issue an injunction or restraining order to restrain certain violations of section 301 of the Act. Under section 303(a)(1) of the Act (21 U.S.C. 333(a)(1)), imprisonment of not more than one year or a monetary fine, or both, may be imposed against any person who violates a provision of section 301 of the Act. Under section 304 of the Act (21 U.S.C. 334), any drug that is misbranded when introduced into or while in interstate commerce, or while held for sale after shipment in interstate commerce, is subject to seizure while in interstate commerce or anytime thereafter.[7] In addition, after entry of a court decree, any such misbranded drug may be disposed of by destruction or sale as the court may direct and in accordance with the Act.[8] Thus, in the event the Agency determines that a drug product is misbranded in violation of the Act, the Agency may pursue various types of enforcement action against the product and/or the product's manufacturer or distributor.

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[5] See section 502(a)-(c), (e)-(j), (n), and (p) of the Act (21 U.S.C. 352(a)-(c), (e)-(j), (n), and (p)).

[6] In addition, under the Act, the following acts and the causing thereof are prohibited: the misbranding of any drug in interstate commerce (section 301(b)); the receipt in interstate commerce of any drug that is misbranded, and the delivery or proffered delivery of such drug for pay or otherwise (section 301(c)); and the misbranding of a drug resulting from the alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a drug while it is held for sale after shipment in interstate commerce (section 301(k)).

[7] See section 304(a)(1) of the Act.

[8] See section 304(d)(1) of the Act.

In the Petition, you request that we determine that the products identified above are misbranded in violation of the Act. As described above, the misbranding of a drug introduced or delivered for introduction into interstate commerce or the manufacture of any drug that is misbranded is a prohibited act and is subject to enforcement actions. Therefore, your request is, in effect, a request that we take enforcement action against the companies that you assert are marketing misbranded drug products and/or the products themselves. This request is not an appropriate request for a citizen petition. Decisions with respect to initiating enforcement actions are generally made by the Agency on a case-by-case basis and are within the discretion of the Agency. Requests for the Agency to initiate enforcement actions are not within the scope of FDA's citizen petition procedures (see 21 CFR 10.30(k)). Therefore, the Petition is denied.

We nevertheless appreciate the information that you provided. Such information often helps us to identify problems with products and possible violations of the laws and regulations that we enforce.

Sincerely,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research