DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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David L. Rosen, B.S. Pharm., J.D.
Foley & Lardner LLP
3000 K Street, N.W.
Suite 500
Washington, D.C. 20007-5143

Re: Docket No. FDA-2006-P-0020

Dear Mr. Rosen:

This letter responds to your citizen petition (Petition) dated August 7, 2006.[1] The Petition requests that the Food and Drug Administration (FDA or Agency) investigate and take regulatory enforcement action as necessary and appropriate to protect surgical patients from what you describe as a potential significant safety risk in connection with Propofol Injectable Emulsion marketed by Bedford Laboratories (Bedford) (Petition at 1, 5).

You assert that independent laboratory testing indicates that the Bedford Propofol Injectable Emulsion product presents an unacceptable risk of infection due to the product's failure to adequately inhibit microbial growth in the event of extrinsic contamination (Petition at 2). Specifically, you claim that the independent test data indicate a strong probability that the product fails to adequately limit the growth of two organisms, *E. coli* and *C. albicans*, when compared to the reference listed drug, Diprivan (Petition at 5). As a result, you assert that the product appears to be adulterated within the meaning of section 501(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)) (Petition at 1).

You request that the Agency investigate and "take regulatory enforcement action as necessary to protect patients from this potential serious health risk" (Petition at 5).[2] 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.

[1] The Petition was originally assigned docket number 2006P-0311/CP1. The number was changed to FDA-2006-P-0020 as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008.

[2] Bedford's Propofol Injectable Emulsion product 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).

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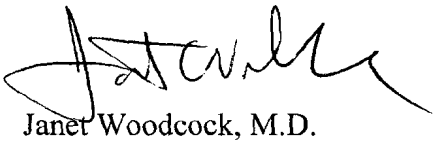
We nevertheless appreciate the information that you provided. Such information often helps us to identify problems with products and possible violations of the laws and regulations that we enforce.

Sincerely,



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