DEPARTMENT OF HEALTH & HUMAN SERVICES

DEC 1 8 2013

Food and Drug Administration
Rockville MD 20857

Carey Nuttall
Patton Boggs LLP
Attorney for Eclat Pharmaceuticals, LLC
2550 M Street, NW
Washington, DC 20037-1350

Re: Docket No. FDA-2013-P-1000

Dear Mr. Nuttall:

This letter responds to your citizen petition received on August 15, 2013 (Petition). The Petition requests that the Food and Drug Administration (FDA or the Agency) take immediate enforcement action against unapproved drug products being illegally marketed as an alternative to an existing FDA-approved drug product and to secure the removal of these products from the market (Petition at 1).

More specifically, you request that FDA immediately remove alleged unapproved neostigmine methylsulfate injectable drug products marketed by the following companies because they are competing with an FDA-approved drug product (new drug application 204078, Bloxiverz (neostigmine methylsulfate) injection):

Cardinal Health (1 milligram/milliliter (mg/mL))
West-Ward Pharmaceuticals Corp. (0.5 mg/mL and 1 mg/mL)
Fresenius Kabi USA, LLC (0.5 mg/mL and 1 mg/mL)
American Regent, Inc. (0.5 mg/mL and 1 mg/mL)
General Injectables & Vaccines, Inc. (1 mg/mL)

(Petition at 1).

You also assert that these products are marketed with incomplete labeling that may raise potential safety risks and may violate the Federal Food, Drug, and Cosmetic Act (FD&C Act) in other ways (Petition at 1).

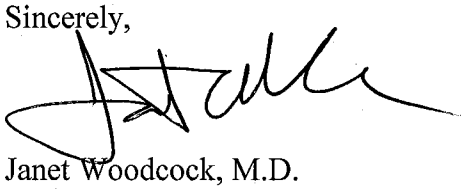
Decisions with respect to initiating enforcement action are generally made by the Agency on a case-by-case basis and are within the discretion of the Agency.[1] Section 10.30 of FDA's regulations governs the submission and review of citizen petitions. Per § 10.30(k), § 10.30 does not apply to "referral of a matter to a United States attorney for the initiation of court enforcement action and related correspondence . . . ." Agency decisions to take enforcement actions are decisions related to referral of a matter to a United States attorney for the initiation of court enforcement action for violations of the FD&C Act. Accordingly, requests for the Agency

[1] Federal courts reflect this same principle, namely that agency decisions relating to enforcement rest within the agency's discretion and are not subject to review. *Heckler v. Chaney*, 470 U.S. 821 (1985); *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594, 600-601 (1950).

to initiate enforcement actions are not within the scope of FDA's citizen petition procedures and this request is not an appropriate request for a citizen petition. Therefore, the petition is denied.

We nevertheless appreciate the information you provided. This type of information is often helpful for us to identify problems with marketed products and possible violations of the laws and regulations that we enforce. We take complaints seriously, and we will evaluate this matter to determine whether follow-up action is appropriate.

Sincerely,



Janet Woodcock, M.D.
Director
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