



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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November 26, 2013

J. Michael Nicholas, Ph.D.
Vice President, Global Specialty Medicines
Teva Pharmaceutical Industries Ltd.
41 Moores Road, P.O. Box 4011
Frazer, PA 19355

Dear Mr. Nicholas:

Your petition to the Food and Drug Administration requesting the Agency to refrain from approving any new rescue inhalers (brand or generic) unless those inhalers contain a dose counter; and implement a plan to transition already approved rescue inhalers without a dose counter to versions that incorporate an integrated dose counter, was received by this office on 11/15/2013. It was assigned docket number FDA-2013-P-1505/CP1, and it was filed on 11/26/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in cursive script, reading "Karen Kennard", is positioned above the typed name.

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)