DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

August 15, 2013

FILE COPY

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

Dear Ms. Nuttall:

Your petition to the Food and Drug Administration on behalf of Éclat Pharmaceuticals, LLC requesting the Agency to 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, was received by this office on 8/15/2013. It was assigned docket number FDA-2013-P-1000/CP1, and it was filed on 8/15/2013. 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,

Karen Kennard

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