DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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September 5, 2013

Horst G. Zerbe
President and CEO
IntelGenx Corp.
6425 Abrams
Saint-Laurent, Quebec
Canada, H4S 1X9

Dear Mr. Zerbe:

Your petition to the Food and Drug Administration requesting the Agency to designate the Rizatriptan Oral Film, when approved pursuant to section 505(b )(2) of the Federal Food, Drug and Cosmetic Act, as AB relative to the Reference Listed Drug (RLD), Maxalt-MLT® (Merck, NDA 20-865), was received by this office on 8/22/2013. It was assigned docket number FDA-2013-P-1058/CP1 and it was filed on 8/22/2013. 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)