



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

December 21, 2005

FILE COPY

Mr. Robert M. DeWitty, Esq.
Vigconic (International) Ltd.
111 S. Calvert Street, Suite 2700
Baltimore, Maryland 21202

Dear Mr. DeWitty:

Your petition requesting the Food and Drug Administration to take the administrative action of clarifying, in writing, an FDA letter received in response to a pre-market notification for VI-28, was received by this office on 12/19/2005. It was assigned docket number 2005P-0495/CP 1 and it was filed on 12/21/2005. 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,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2005P-0495

ACK 1