DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Barile & Associates, Inc.
c/o Diane Sudduth, MS, DVM, MPH
Senior Quality Consultant
8282 Shadow Wood Blvd.
Coral Springs, FL 33071

OCT - 1 2007

Re: C070237
Product Name: Undetectable Nasal Insert
Dated: July 13, 2007
Received: July 24, 2007

Dear Dr. Sudduth:

We have reviewed the above referenced request for information, submitted in accordance with Section 513(g) of the Federal Food, Drug, and Cosmetic Act (Act), regarding the regulatory requirements applicable to the Undetectable Nasal Insert. As described in your submission, we believe that your product is not a "device" as that term is defined in Section 201(h) of the Act. Therefore, you are not required to comply with the requirements of the Act. Please note, if you later revise your indications to add medical claims, you may need a premarket notification [510(k)] submission.

If you have any questions regarding this letter, please contact Mr. Bryan Benesch, Office of Compliance (OC), at 240-276-0141, or for general questions please contact the Division of Small Manufacturers International and Consumer Assistance at its toll free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph. D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and Radiological Health