



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

January 28, 2013

**FILE COPY**

Virginia Carman  
Associate Director, Regulatory Affairs  
IGI Labs, Inc.  
105 Lincoln Ave.  
P.O. Box 687  
Buena, NJ 08310

Dear Ms. Carman:

Your petition to the Food and Drug Administration requesting a determination whether Cordran (flurandrenolide) Ointment USP, 0.05% (NDA# 12-806 - NDA Holder Aqua Pharmaceuticals) has been voluntarily withdrawn from sale for safety or effectiveness reasons, was received by this office on 1/28/2013. It was assigned docket number FDA-2013-P-0113/CP1, and it was filed on 1/28/2013. 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,

Gloria Ortega  
Administrative Proceedings Officer  
Division of Dockets Management  
FDA/Office of the Executive Secretariat (OES)