

FDA Background

Today® Sponge

NDA # 18-683

Allendale Pharmaceuticals

July 12, 2000 NDAC meeting

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Executive Summary

Current Labeling-1991 Submission

**FDA Proposed Labeling Revision 5/2000
Package Carton (Drug Facts Format)
• Consumer Leaflet (Package Insert).**

OPDRA Safety Review

DOTCDP Medical Officer's Review

Citizens Petitions

- **May 1983 Petition**
- **June 1983 Petition**
- **February 1992 Petition**

FDA response August 1997

- **April 24, 2000 Petition**