

Proposed Meeting Agenda: ChloroPrep® with Tint

Meeting Date: June 14, 2006 Location: Building 22, Room 1309 Time: 9:00 a.m.
White Oak Campus

External Participants:

Linda McBride, R.Ph., Senior Director Regulatory Affairs, Medi-Flex, Inc.
James Bardwell, Manager of Product Development, Medi-Flex, Inc.
Daniel E. Troy, Esq., Sidley Austin LLP (Attorney for Medi-Flex, Inc.)
Gary L. Veron, Esq., Sidley Austin LLP (Attorney for Medi-Flex, Inc.)

Meeting Chair (FDA):

Sponsor Lead: Linda McBride

Introductions

Meeting Objectives:

1. Discuss the scope of Medi-Flex's three-year exclusivity for its product, ChloroPrep® with Tint, particularly with respect to ANDA 77-271 submitted by Cardinal Health, Inc..
2. Discuss the application of Medi-Flex's efficacy study regarding the tint ingredient for ChloroPrep® with Tint to ANDA 77-271, which includes a different color tint.
3. Explain Medi-Flex's position and respond to any FDA questions or concerns.

Meeting Discussion Items:

<u>Name of Presenter</u>	<u>Discussion Item</u>	<u>Time Allocated</u>
1. Linda McBride	Overview of the situation	10 minutes
2. Linda McBride	Summary of the approval history for ChloroPrep® with Tint, particularly the required studies; FDA's exclusivity summary; and description of similar studies for ChloroPrep® One-Step	10 minutes
3. James Bardwell	Analysis of Medi-Flex's study regarding the tint ingredient and application to Cardinal's product	15 minutes
4. Dan Troy	Cardinal's ANDA is improper	10 minutes
5. All Participants	General discussion	15 minutes

Summarize Agreed-upon Points/Unresolved issues

Discuss any necessary follow-up

Close meeting