Minutes of Meeting

Subject: Exclusivity of ChloraPrep with Tint (Medi-Flex NDA 20-832), Cardinal's ANDA 77-271, and the citizen petition filed by Medi-Flex in Docket No. 2005P-0458

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

FDA Participants:

Elizabeth Dickinson, Office of Chief Counsel
Dave Read, Regulatory Counsel, Office of Generic Drugs (OGD)
Don Hare, Special Assistant to the Director, OGD
Michael Bernstein, Dir., Div. of Reg. Pol. II, Office of Regulatory Policy (ORP)
Marguerita Sims, Regulatory Counsel, ORP
Susan Johnson, Supervisory Pharmacist, Office of Nonprescription Drugs (ONP)
Debbie Lumpkins, Microbiologist, ONP, Div. of Nonprescription Reg. Development
Leah Christl, Supervisory CSO, ONP, Div. of Nonprescription Clin. Eval. (DNCE)
Laura Shay, Dir. of Reg. Affairs, ONP, DNCE

Participants for Medi-Flex, Inc.:

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

This meeting was held at the request of Medi-Flex. It lasted one hour and closely followed the agenda and slides presented by Medi-Flex (attached). Ms. McBride began the discussion with a brief history of the company in general and the chlorhexidine gluconate (CHG) products in particular. She stressed that an important aspect of the company is the development of new embodiments of CHG products in response to customer need. She distributed samples of three of the products that were part of the discussion: (1) ChloraPrep with Tint 26 mL, (2) ChloraPrep with Tint 10.5 mL, and (3) untinted Chloraprep 10.5 mL. She said the tinted products were developed at the request of health care practitioners due to the fact that it is often the case that a nurse or technician will prep a patient, not the surgeon, and that a tint can aid the surgeon in seeing exactly the area that has been covered. The tint also helps in the detection of pooling. The untinted products remain useful when the prep and the procedure are performed by the same person.

As noted in slide #10, Medi-Flex performed a clinical log reduction study that used ChloraPrep with Tint and povidone-iodine as the control. They also did a volume study, the primary purpose of which was to investigate the problem of pooling. Medi-Flex acknowledged that the volume study was specific to the 26 mL volume and was not relevant to the 10.5 mL products. These studies formed the basis of the 3-year exclusivity granted to ChloraPrep with Tint 26 mL (approved May 3, 2005). Medi-Flex requested that the exclusivity embrace the recently

approved ChloraPrep with Tint 10.5 mL (approved April 3, 2006). FDA explained that this probably can be done under the so-called "umbrella policy," i.e., that ChloraPrep with Tint 10.5 mL would not get a separate exclusivity period, but could be included in the remainder of the exclusivity period that expires on May 3, 2008, to the extent that the exclusivity was granted for clinical studies showing the effectiveness of the tinted product, as distinct from the safety (volume) studies related to the 26 mL volume product.

With respect to the Cardinal ANDA (and the issues raised in the citizen petition) it is Medi-Flex's position that Cardinal should be required either (1) to use Medi-Flex's ChloraPrep with Tint 10.5 mL as the RLD, and not the untinted ChloraPrep 10.5 mL, or (2) if Cardinal is required to conduct clinical trials as a condition of approval, to submit their application as a 505(b)(2) application, not as an ANDA under 505(j).

FDA took Medi-Flex's position under advisement. While there was general agreement about the factual aspects of the case, no decisions were made with respect to the issues raised by Medi-Flex in its citizen petition.

Minutes prepared by Dave Read.