

MINUTES OF THE TELECONFERENCE
OF THE PQRI PSD MASS BALANCE WORKING GROUP ON
25 FEBRUARY 2002

I. PARTICIPANTS

Terry Tougas (Boehringer Ingelheim), Chair
Mary Devlin Capizzi (IPAC-RS)
Ken Furnkranz (FDA)
Martin Lavery (Aventis)
Lana Lyapustina (IPAC-RS)
Jolyon Mitchell (Trudell Medical)
Lee Nagao (IPAC-RS)
Brian Rogers (CDER/FDA)
Bruce Wyka (Schering-Plough)
Kahkashan Zaidi (USP)

II. DISCUSSION

During the teleconference, Working Group members:

- reviewed the revised draft work plan dated 24 February;
- discussed additional minor revisions;
- approved the work plan, with the additional minor revisions, for submission to the PQRI Drug Product Technical Committee; and
- agreed to review and revise the timelines of the work plan at the next Working Group's teleconference.

The particular points discussed during the teleconference included the following:

- while some liquid suspensions may be characterized as "stable", aerosols (suspensions of liquid or solid particles in the air) are inherently unstable;
- it will be important to determine, in due time, the exclusion/inclusion criteria for products to be studied; and
- the USP definition of the "minimum recommended dose" should be added to Appendix B of the work plan.

III. NEXT TELECONFERENCE/MEETING

The next teleconference of the PSD Mass Balance Working Group is scheduled for **Monday, 25 March at 10:00 AM (US ET)/15:00 (UK)**.

IV. ADDRESSEES

PQRI PSD Mass Balance Working Group:

Ken Furnkranz (CDER/FDA)
Martin Lavery (Aventis)
Margareth Marques (USP)
Deborah Miran (GPhA)
Jolyon Mitchell (Trudell Medical)

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Jeffrey Blumenstein (Pfizer, DPTC)
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Chris Moreton (DPTC)
Guirag Poochikian (FDA, DPTC)
PQRI PSD Profile Comparisons Working Group

Finalized on 13 May 2002