

MINUTES OF THE TELECONFERENCE
OF THE PQRI PSD MASS BALANCE WORKING GROUP ON
3 March 2003

I. PARTICIPANTS

Terry Tougas (Boehringer Ingelheim), Chair	Lana Lyapustina (IPAC-RS)
Dave Christopher (Schering-Plough)	Jolyon Mitchell (Trudell Medical)
Paul Curry (USP Aerosols Expert Committee)	Brian Rogers (FDA)
Bill Doub (FDA)	Helen Strickland (GlaxoSmithKline)
Ken Furnkranz (FDA)	Yi Tsong (FDA)
Martin Lavery (Aventis)	Bruce Wyka (Schering-Plough)

II. OPENING

Dr. Tougas proposed, and the participants agreed on the following objectives for the teleconference: (i) to discuss a draft presentation for the PQRI Workshop to be held on 3-4 April (<http://www.pqri.org/events/workshops/pqri/040403pqri.pdf>); (ii) to review updates on other activities; and (iii) to agree on next steps.

The Working Group approved the draft minutes of the 24 January teleconference.

III. DISCUSSION

Draft Slides

The Working Group reviewed the draft presentation slide by slide and discussed the following points:

- The language from the finalized Guidance for *Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products* should be included in the slides. Full titles of the Guidances should be used.
- According to Dr. Rogers, even though a mass balance measurement may not be the best test of product quality as compared to DCU, it may still be used as a product quality test. A clarification to this effect should be added to the slides as a footnote.
- Even though originally, the experiment of CI variability had as one its objectives a comparison between the total emitted dose determined by DCU and that determined by CI MB, in subsequent discussions the Working Group agreed that the two need not be compared because MB is not a surrogate for DCU. A clarification to this effect should be added to the slides as a footnote.
- Exact language regarding checklists should be quoted from the Good Cascade Impactor Practices paper.

- 28 • Specific recommendations for investigating product failures are outside the scope of
29 the Good Cascade Impactor Practices paper. A suggestion that the APSD
30 measurement be scheduled to permit subsequent DCU testing within the label claim
31 number of actuations may be mentioned in the oral presentation at the Workshop
32 but need not be included in the slides.
- 33 • According to Dr. Rogers, it remains to be proven that MB should not be used as a
34 product specification. This should be reflected in the slide concluding the GCIP
35 section of the presentation.
- 36 • In the CI variability study, a range of products should be investigated. Desired
37 product characteristics (*e.g.*, device type, strength) will be discussed by the Working
38 Group at the next meeting.

39 *Other Updates*

40 Ms. Strickland and Mr. Christopher confirmed that the statistical design of the CI
41 variability experiment will be discussed during the next meeting of the Working Group.

42 To date, no response has been received for the MB/APSD failure cause survey. This
43 issue will be discussed at the next meeting. Handouts of blank forms for the survey should be
44 made available during the upcoming PQRI Workshop, and the reference to the survey website
45 should be included in the Working Group's slide presentation.

46 **IV. AGREED ACTIONS**

- 47 • Following the teleconference, the slides will be revised and circulated to the Working
48 Group for final review. The slides will be submitted to Ms. Gantt at the close of
49 business on Monday, 3 March.
- 50 • At the Workshop, blank copies of the MB/APSD failure causes questionnaire should
51 be made available to the participants, and the slides should include the internet
52 address for the survey. In addition, the Working Group's presenters should
53 emphasize the importance of this and future survey on MB limits, and request that
54 industry provide data.
- 55 • At the next meeting, the Working Group will review (i) status of responses to the MB
56 and APSD failure causes, and (ii) considerations for designing CI variability
57 experiment.

58 **V. NEXT TELECONFERENCE/MEETING**

59 The next meeting of the PQRI PSD Mass Balance Working Group is scheduled for
60 **Thursday, 3 April 2003, at 2:45 - 4:00 PM EST**, in Arlington, VA. (Due to the cancellation, in
61 late March, of the PQRI Workshop, the meeting of the Working Group was replaced with a
62 teleconference scheduled for the same time).