Final Minutes- April 22, 2002
Nonprescription Drugs Advisory Committee with consultants from Pulmonary - Allergy and Dermatological Drugs Advisory Committee

Food and Drug Administration
Center for Drug Evaluation and Research
Holiday Inn, Bethesda

Claritin for OTC Use (loratadine, Schering Plough)
NDA 19-658, NDA 20-704, NDA 20-641

Prior to the meeting, the committee had reviewed background material from Schering Plough and from the FDA. The meeting was called to order by Louis Cantilena, M.D., Ph.D. and Sandra Titus, Ph.D. read the conflict of interest statement into the record. There were approximately 120 people in attendance.

Attendance:
NDAC Members Present: Louis Cantilena, M.D.., Ph.D., NDAC Chair and Chair of the meeting, Edwin Gilliam, Ph.D., Julie Johnson, Pharm.D., Hari Sachs, M.D., Edward Krenzelok, Francis Lam, Pharm.D., Donald Uden, Pharm.D., Henry Williams, M.D., Leslie Clapp, M.D., Frank Davidoff, M.D., Alastair Wood, M.D.

NDAC Members Absent: Richard Neill, M.D.

NDAC Voting Consultants: Ralph D'Agostino, Ph.D.

Pulmonary-Allergy Voting Consultants: Mark Dykewicz,M.D., Jesse Joad, M.D., Stan Szefler, M.D.

Dermatological Voting Consultants: Lloyd King, M.D., William Rosenberg M.D.,

Industry Guest: (non voting) Michael Alfano, M.D.

FDA Participants:, Robert Temple, M.D., Sandra Kweder, M.D., Jonca Bull, M.D., , Charles Ganley, M.D., Jonathan Wilkin, M.D., Linda Katz, M.D., Badrul Chowdhury, M.D., Ph.D., Mathew Holman, Ph.D.

FDA: Overview Of Today's Issues
Charles Ganley, M.D., Director OTCDP, outlined the purpose of the meeting.

Schering Presentations:

John Clayton, Ph.D, Senior VP Scientific and Regulatory Affairs presented an overview. Eugene W. Monroe, M.D. Department of Dermatology from the Medical College of Wisconsin and consultant to Schering presented a clinical overview of urticaria. Stephen Neuman, presented the CIU studies and Dr. Clayton concluded with a risk benefit analysis. Questions followed the presentations.

FDA Presentations:

Jonathan Wilkin, Director, Dermatologic Drugs presented an Overview on Urticaria. Badrul Chowdhury, M.D., Ph.D described the clinical study design issues for the Approved H1 Antihistamines with CIU Indication. Matthew Holman, Ph.D., presented OTC Issues: US Regulatory History, Foreign Marketing and Label Comprehension Study. Charles Ganley, M.D. concluded the presentations by raising Issues for the Committee's deliberation on the use of Claritin for Urticaria in the OTC setting.

Open Public Hearing

Gary Kay, Ph.D., Janet Engle, PharmD., and Joseph Ferguson, M.D. presented.

Questions for Committee Deliberation:

1. Is urticaria a disease process appropriate for an OTC indication?

The committee altered this question to:

Could urticaria be a disease process appropriate for an OTC indication?

Yes = 16 No=0 (one member absent for vote)

a. If yes, should the indication be for chronic idiopathic urticaria (CIU)/hives or should it be broader such that it includes acute urticaria / hives?

Yes for broader indication = 14

Possibly broader =1 (because of concern for anaphalaxis)

Broader if stated treat hives after seeing an MD =1 (because we would avoid a misdiagnosis and closer to what the sponsor is seeking)

There was consensus that everyone with hives would be likely to use a product that was approved for any form of hives.

2. If your answer to Question 1 is "yes," are there sufficient data to support an OTC switch of loratadine for CIU or a more general urticaria claim?

The committee felt that it was too difficult to consider a broad indication, which is desirable as the context for this question. Hence the question became:

Are there sufficient data to support an OTC switch of loratadine for CIU?

Yes for CIU indication =16 No=0

(One person not present for vote)

Are there sufficient data to support an OTC switch of loratadine for general hives?

Yes for general hives = 0 **no for general hives = 11**
Don't know/insufficient data =5

If not, what other types of data are needed (such as clinical trial(s) for efficacy, safety, label comprehension, or actual use)?

The following viewpoints were expressed:

Would be nice to see a Meta -analysis of all the research on hives.

Would be nice to know if people could understand what CIU is versus hives so that it would be labeled appropriately.

Probably don't need clinical trials because the data are probably already out there.

Are there studies that use it for acute hives? (Sponsor thought there were not any studies)

A label comprehension study to see if effectively labeled

Seems negative to stick with CIU indication when know that the broader indication will occur.

Use of loratadine sounds safe and cannot learn a lot from spontaneous reports.

Even without data, indication should go just "hives" because it is more understandable.

Additional Studies that included subpopulations (underrepresented) would be needed to go forward with a more general indication.

3. If your answer to Question 2 is "yes," what are your recommendations for appropriate labeling of loratadine, with regard to indications, warnings, and directions?

The following comments were individually suggested and there was no attempt to get consensus:

Label should maximize warning for anaphylaxis

Label should indicate that vascular process is possible

Clear definition of chronic or recurrent and if possible provide a picture.

Use of the term "unexplained hives that may keep coming back", may be appropriate for CIU explanation.

Blister packs may be a problem because information that a consumer needs from the packaging could get lost.

Call it hives rather than CIU

Use a list, such as 10 reasons to consult a doctor.

How long should one continue treatment?

Call 911 if respiratory problems.

Be careful not to overstuff the label and need to prioritize information.

Stress that it is a once a day pill.

If chronic label then a statement that you saw a doctor and he did not know the cause of the hives (explain idiopathic).

If broader claim, would take out precaution.

A verbatim transcript of this meeting will be available on the FDA's Dockets Management Branch Website approximately 30 days after the meeting. The address is HTTP://www.fda.gov/ohrms/dockets/ac/acmenu.htm.

I certify that I attended the April 22, 2002 meeting of the Nonprescription Drugs Advisory Committee and that these minutes accurately reflect what transpired.

Sandra Titus, Ph.D.	Date	Louis Cantilena, M.D., Ph.D.	Date
Executive Secretary, NDAC		Chair, NDAC	