Questions: April 22, 2002
Nonprescription Drugs Advisory Committee with consultants from
Pulmonary - Allergy and Dermatologic Drugs Advisory Committees

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

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

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

    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?

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

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

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