Dermatologic and Ophthalmic Drugs Advisory Committee
Meeting # 54

QUESTIONS

1. Is there sufficient evidence for effectiveness of Protopic, 0.03%, in the treatment of atopic dermatitis?

2. Is there sufficient evidence for superior effectiveness of Protopic 0.1% compared to 0.03%...
a. ...in adults?
b. ...in children?

3. Has the safety profile of Protopic in the treatment of atopic dermatitis been adequately determined for unrestricted chronic therapy as a first-line treatment...
a. ...in adults for both 0.03% and 0.1%?
b. ...in children for both 0.03% and 0.1%?

4. The proposed indication for Protopic, which would allow for both 0.03% and 0.1%, for unrestricted chronic therapy, as a first-line treatment of atopic dermatitis, in adults and children 2 years and older, may be decomposed into the following elements which may be reconstructed into indication(s):

DECISION TABLE

	Adults	Children 2 years and up
Unrestricted chronic therapy vs time-limited acute therapy?	?	?
First-line vs second-line treatment?	?	?
0.03%, 0.1%, both, or neither	?	?

Is approval of Protopic recommended and, if so, under what conditions [concentration(s), first- vs second-line, chronic vs (time-limited) acute therapy] in which age groups?

5. Are there additional studies needed to provide information important for the labeling of Protopic? If so, what studies are recommended? (Consider the issues of lymphoma, local suppression of immunity, photocarcinogenesis, etc.)