

26

By Hand

April 4, 2001

The Honorable Bart Stupak
U.S. House of Representatives
2348 Rayburn House Office Building
Washington, D.C. 20515-2201

Dear Representative Stupak:

I am writing to provide you with an update regarding activities undertaken by Hoffmann-La Roche Inc. (Roche) with respect to Accutane® (isotretinoin). I would also like to take this opportunity to provide additional information to supplement a conversation between one of Roche's federal government affairs consultants and a member of your senior staff.

First, as you may be aware, FDA has approved an Informed Consent/Patient Agreement form that must be signed by both patients and physicians (and parents if the patient is a minor) before a prescription is issued. Separately, a new Medication Guide has been approved that is to be dispensed with each Accutane prescription at the pharmacy. Attached please find a copy of both documents, which have previously been provided to your staff. Along with other educational measures, use of these documents will assist prescribers and pharmacists in assuring that patients, both male and female, are explicitly informed about psychiatric events in the patient population likely to be treated with isotretinoin.

In addition, I would like to address concerns raised recently by your staff with respect to Roche's agreement to suspend televised acne education. Your staff indicated this may not have been sufficiently responsive to your recommendations with respect to direct-to-consumer (DTC) advertising to children because Roche continues to use non-televised acne awareness messages. As was indicated in the October 17, 2000, letter from former Roche CEO Patrick Zenner, Roche does not conduct DTC advertising for Accutane; the only branded advertising of Accutane is within the product professional label to dermatologists. Roche does, however, provide acne educational information to consumers that does not mention our product Accutane, and is solely intended to raise awareness that there are treatments available for acne from dermatologists. Such materials address general acne concerns, and we believe they provide important health information, particularly given the relative lack of public resources dedicated to acne.

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faxed to BTS/m...
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I know that this issue is of utmost importance to you, and I hope that this information addresses the questions and concerns articulated by your staff. Thank you for the opportunity to provide this update.

Sincerely,

A handwritten signature in black ink, appearing to read "Russell Ellison". The signature is fluid and cursive, with a large initial "R" and "E".

Russell Ellison

RHE/cds

Attachments: 2

cc: The Honorable Thomas M. Barrett
The Honorable Sherrod Brown
The Honorable Ed Bryant
The Honorable Marge Roukema
The Honorable Zach Wamp
The Honorable Henry Waxman