



July 26, 2005

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket No. 2005D-0203

Dear Sir or Madam:

Provided herewith are two (2) copies of Alcon's comments regarding FDA's Draft Guidance on "Safety Testing of Drug Metabolites".

If you have any questions regarding these comments, please contact me via e-mail at garry.heidel@alconlabs.com or via telephone at (817) 551-6813.

Sincerely,

A handwritten signature in blue ink that reads "Garry G. Heidel". The signature is written in a cursive, flowing style.

Garry G. Heidel
Director Regulatory Compliance
Alcon Research, Ltd.

Attachment

Alcon's comments regarding FDA's Draft Guidance on "Safety Testing of Drug Metabolites"

Alcon submits the following comment regarding the Draft Guidance on "Safety Testing of Drug Metabolites:

Pharmaceuticals applied topically (e.g. dermal and ocular routes of administration) may need studies of major metabolites. However, pharmaceuticals showing poor systemic exposure from topical routes in humans may not need systemic studies assessing the toxicity of major metabolites due to the low level of systemic exposure. Pharmaceuticals administered by the ocular route may not require studies of unique major metabolites unless there is cause for concern or unless there is significant systemic exposure.