



January 9, 2006

Mr. Matias Diez  
Manager, Regulatory Affairs  
Mead Johnson Nutritionals  
2400 West Lloyd Expressway  
Evansville, IN  
47721-0001

Dear Mr. Diez:

I am writing to correct three typographical errors in the letter of December 27, 2005, from Scott Gottlieb, M.D., Deputy Commissioner for Medical and Scientific Affairs, objecting to the notification submitted by Mead Johnson Nutritionals for extensively hydrolyzed casein. The corrections are as follows:

Page two, second paragraph, second sentence, should read "These studies are not relevant to the question of whether this EHC contains protein that is allergenic for milk-allergic individuals."

Page four, first paragraph, fourth sentence, should read: "No information is provided on the sensitivity of the method or the casein content of the original sample and it is therefore not possible to determine the maximal level of casein that might be present in a batch of EHC screened by this ELISA."

Page four, first paragraph, ninth sentence, should read: "This is particularly significant given the lack of information about the source material for EHC and because intact  $\beta$ -lactoglobulin, another allergenic milk protein (derived from whey), has been detected in Mead Johnson EHC formulas (Mäkinen-Kiljunen et al., 1993; Rosendal and Barkholt, 2000)."

Please contact me at (301)436-1589 if you have any questions about these corrections.  
Thank you.

Sincerely,

Catherine L. Copp  
Policy Advisor  
Office of Regulations and Policy

2005N-0416

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