



DEPARTMENT OF HEALTH & HUMAN SERVICES

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**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Food and Drug Administration  
Detroit District  
1560 East Jefferson Avenue  
Detroit, MI 48207-3179  
Telephone: 313-226-6260

**WARNING LETTER**  
2001-DT-28

August 29, 2001

Peter R. Dolan, President  
Bristol-Myers Squibb Company  
345 Park Avenue  
New York, NY 10154

Dear Mr. Dolan:

We are writing to you because of a serious regulatory problem involving infant formula manufacturing operations at Mead Johnson Nutritionals, Evansville, Indiana.

Mead Johnson Nutritionals recently recalled Enfamil Nutramigen Hypoallergenic Formula, Ready to Use/Do Not Add Water in one quart cans and Enfamil Nutramigen Hypoallergenic Formula Powder in one pound cans after receipt of a consumer complaint that the Spanish language instructions for use were different than the English language instructions for use.

Our review of the label for Enfamil Nutramigen Hypoallergenic Formula, Ready to Use/Do Not Add Water in one quart cans has confirmed that the Spanish language version of the instructions for use direct dilution of the product 1:1 with water, while the English language version of the instructions for use direct use of the product without dilution. Our review of the label for Enfamil Nutramigen Hypoallergenic Formula Powder in one pound cans has confirmed that the Spanish language version of the instructions for use directs the preparation of the formula by mixing powder with water and then further diluting the prepared formula 1:1 with additional water. The English language version of the instructions for use does not direct further dilution of the prepared formula.

Our review has concluded that the English language instructions for use on these infant formulas will provide adequate infant nutrition, if followed, but that the Spanish language instructions for use will not provide the nutrients required by Section 412 (i) of the Federal Food, Drug, and Cosmetic Act [the Act].

Therefore, we conclude that Enfamil Nutramigen Hypoallergenic Formula, Ready to Use/Do Not Add Water in one quart cans and Enfamil Nutramigen Hypoallergenic Formula Powder in one pound cans are adulterated infant formulas within the meaning of Section 412(a)(1) of the Act and Title 21, Code of Federal Regulations, Part 107, in that the Spanish language instructions for use do not provide the nutrients required by Section 412(i) of the Act.

We further conclude that the Spanish language instructions for use cause Enfamil Nutramigen Hypoallergenic Formula, Ready to Use/Do Not Add Water in one quart cans and Enfamil Nutramigen Hypoallergenic Formula Powder in one pound cans to be misbranded within the meaning of Section 403(a)(1) of the Act because the Spanish language instructions for use are misleading in that they direct the incorrect dilution of the products.

An inspection was conducted at Mead Johnson Nutritionals, Evansville, Indiana on July 9-10, 2001 to determine if these violations had resulted from systemic causes, or from human error. This inspection revealed that Mead Johnson Nutritionals has inadequate controls in place to prevent the recurrence of the same, or similar, violations in the future.

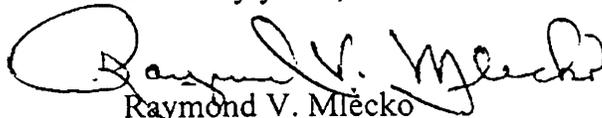
We acknowledge receipt of a response letter [dated July 17, 2001 from Randall K. Alsman to Raymond V. Mlecko] to the list of observations issued at the conclusion of this inspection.

Failure to prevent future violations of this nature may result in regulatory action, such as seizure, injunction or prosecution, without further notice. It is your responsibility to ensure that products marketed by your firm meet all of the requirements of the Act and the regulations promulgated thereunder.

Please notify us in writing, within 15 working days of your receipt of this letter, of the specific steps you have taken to prevent the recurrence of these types of violations throughout all of the Bristol-Myers Squibb facilities.

Also, we are requesting that you undertake an immediate review of each print run for each in-date infant formula, medical food and food for special dietary use marketed by Bristol-Myers Squibb to determine whether additional labeling errors have escaped detection. Your response should be directed to Ms. Greta Budweg, Compliance Officer, at the above address.

Sincerely yours,



Raymond V. Mlecko  
District Director  
Detroit District

Cc via certified mail: Randall K. Alsman  
President  
Mead Johnson Nutritionals  
2400 W. Lloyd Expressway  
Evansville, Indiana 47721-0001