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SILVER SPRING, MD.

DEPARTMENT OF  
HEALTH, EDUCATION, AND WELFARE  
FOOD AND DRUG ADMINISTRATION  
WASHINGTON 25, D. C.  
April 2, 1957

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Mr. Kenneth D. Barrett  
The Distribution Center, Inc.  
Box 242  
Silver Spring, Maryland  
Dear Mr. Barrett:

In Mr. Cook's absence, I am replying to your letter of February 26 concerning "Dianazono."

We understand from your letter that the Dianazono label will recommend that three tablets be taken per day and will name ferrous gluconate as the ingredient supplying the iron.

If three tablets (the recommended daily dose) supply an amount of ferrous gluconate equivalent to 100 milligrams of elemental iron, we would have no objection to the proposed use for preventing iron deficiency anemia. In this connection, we point out that since the iron content of ferrous gluconate is approximately 12 percent, three tablets of Dianazono would have to contain approximately 0.8 gram of ferrous gluconate in order to provide a daily intake of 100 milligrams of elemental iron.

Assuming that, as finally marketed, the article will provide the equivalent of 100 milligrams of elemental iron in the daily dose and that the only claims made for the article in all of its promotional material is that it is for overcoming iron deficiency anemia and deficiencies of vitamins B<sub>1</sub>, B<sub>2</sub>, C, and nicotinic acid, we have no other significant comment to offer.

Sincerely yours,

*M. S. Yankowitz*

M. S. Yankowitz  
Assistant to the Director  
Bureau of Enforcement