



JUL 12 2002

Ms. Susan D. Brienza
Patton Boggs LLP
Attorneys at Law
1660 Lincoln Street
Suite 1900
Denver, Colorado 80264

Dear Ms. Brienza:

This is in response to your letter to the Food and Drug Administration (FDA) dated April 5, 2002 and amended on April 23, 2002 that was filed with FDA on April 29, 2002. Your notification concerns the new dietary ingredient IronAid™ (Iron Protein Succinylate—an iron-protein complex consisting of ferric iron (5% elemental iron) wrapped in milk casein) (IPS) or ITF 282) that is manufactured by Italfarmaco Spa of Italy, that you represent as a subsidiary, Chemi Nutraceuticals, Inc. (Chemi Nutra in the United States).

The law at 21 U.S.C. 350b(a)(2) requires that a manufacturer or distributor submit certain information to FDA at least 75 days before a new dietary ingredient or dietary supplement containing it is introduced or delivered for introduction into interstate commerce. This information must include the basis on which the manufacturer or distributor has concluded that the new dietary ingredient or a dietary supplement containing it will reasonable be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21 U.S.C. 350b(a)(2), there must be a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is deemed to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

FDA has carefully considered the information in your notification that you relied upon to conclude that IronAid™ will reasonably be expected to be safe and has concerns about your recommended conditions of use. Recommendations to address our concerns are the following:

- Limit daily dosage to an amount that, when combined with food intake, would not deliver more than the upper limit (UL) established by the National Academy of Sciences (NAS):

The UL daily intake of iron is 40 mg for infants and children and is 45 mg for adults.¹ The iron intake estimates from diet are 15-16 mg for infants, 16-18 mg for children 9-13 years, and 29-93 mg for adults.² Because your recommended serving size ranges from 20 mg to 800 mg of IronAid™ IPS (1 to 40 mg of total elemental iron) taken twice per day, your conditions of use could exceed the NAS UL for iron intake.

- Use appropriate packaging and consumer warnings:

Iron-containing dietary supplements must be packaged in compliance with 21 CFR Part 111.50. It has been noted that accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Consumers should be advised to keep the product out of reach of children and, in case of accidental overdose, to call a doctor or poison control center immediately. Further, because the product contains casein, a milk protein, the ingredient list should include this information so that individuals with milk allergies can take appropriate action.

Although we are not finding at this time that the basis on which you have concluded that a dietary supplement containing IronAid™ will reasonably be expected to be safe is inadequate, FDA is not precluded from taking action in the future against a dietary supplement containing IronAid™ if it is found to be adulterated or misbranded. It is the manufacturer's or distributor's responsibility to ensure that any dietary ingredient contained in a dietary supplement is safe and properly labeled. Importantly, new dietary ingredients for use in dietary supplements that FDA has reviewed through the premarket notification process are not "approved" or "authorized" by the agency.

Your notification will be kept confidential for 90 days from the date of its receipt. After June 5, 2002, your notification will be placed on public display at FDA's Dockets Management Branch in docket number 95S-0316. However, any trade secret or otherwise confidential commercial information in the notification will not be disclosed to the public.

Prior to July 28, 2002, you may wish to identify in writing specifically what information you believe is proprietary in your current notification for FDA's consideration.

¹ *Dietary Reference Intakes for vitamin A, vitamin K, arsenic, boron, chromium, coppers, iodine, iron, manganese, molybdenum, nickel, silicon, vanadium, and zinc: a report on the panel on Micronutrients, Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board, Institute of Medicine, 2001.*

² *National Center for Health Statistics, United States Department of Health and Human Services: The Third National Health and Nutrition Examination Survey (NHANES III), 1988-94, United States Department of Health and Human Services, Washington, D.C., 1996.*

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Nevertheless, our Center's Freedom of Information Officer has the authority to make the final decision about what information in the notification should be redacted before it is posted at Dockets

Please contact us at (301) 436-2371, if you have any questions concerning this matter.

Sincerely yours,

A handwritten signature in cursive script that reads "Felicia B. Satchell".

Felicia B. Satchell
Director
Division of Standards
and Labeling Regulations
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition



SEP 5 2002

Ms. Susan D. Brienza
Patton Boggs LLP
Attorneys at Law
1660 Lincoln Street
Suite 1900
Denver, Colorado 80264

Dear Ms. Brienza:

This letter amends and supplants our letter dated July 12, 2002 concerning your notification for the new dietary ingredient IronAid™

Our first letter responded to your letter to the Food and Drug Administration (FDA) dated April 5, 2002 and amended on April 23, 2002 that was filed with FDA on April 29, 2002. Your notification concerns the new dietary ingredient IronAid™ (Iron Protein Succinylate—an iron-protein complex consisting of ferric iron (5% elemental iron) wrapped in milk casein) (IPS) or ITF 282) that is manufactured by Italfarmaco Spa of Italy, that you represent as a subsidiary, Chemi Nutraceuticals, Inc. (Chemi Nutra in the United States).

The law at 21 U.S.C. 350b(a)(2) requires that a manufacturer or distributor submit certain information to FDA at least 75 days before a new dietary ingredient or dietary supplement containing it is introduced or delivered for introduction into interstate commerce. This information must include the basis on which the manufacturer or distributor has concluded that the new dietary ingredient or a dietary supplement containing it will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21 U.S.C. 350b(a)(2), there must be a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is deemed to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

Although we are not finding at this time that the basis on which you have concluded that a dietary supplement containing IronAid™ will reasonably be expected to be safe is inadequate, FDA is not precluded from taking action in the future against a dietary

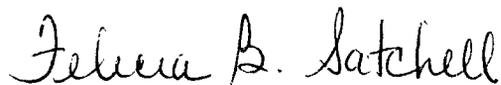
supplement containing IronAid™ if it is found to be adulterated or misbranded. Importantly, new dietary ingredients for use in dietary supplements that FDA has reviewed through the premarket notification process are not “approved” or “authorized” by the agency. Please be advised that it is the manufacturer’s or distributor’s responsibility to ensure that a dietary supplement product marketed in the United States complies with all applicable requirements of the Federal Food, Drug and Cosmetic Act and implementing regulations in Title 21 of Code of the Federal Regulations as well as any other applicable Federal laws and regulations.

Your notification will be placed on public display at FDA’s Dockets Management Branch in docket number 95S-0316. However, any trade secret or otherwise confidential commercial information in the notification will not be disclosed to the public.

We have received your July 19, 2002 letter requesting redaction of information you believe is proprietary in your notification. FDA will consider your request. Nevertheless, our Center’s Freedom of Information Officer has the authority to make the final decision about what information in the notification should be redacted before it is posted at Dockets.

Please contact us at (301) 436-2371, if you have any questions concerning this matter.

Sincerely yours,



Felicia B. Satchell
Director
Division of Standards
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