

July 19, 2002

Susan D. Brienza  
(303) 894-6146  
[sbrienza@pattonboggs.com](mailto:sbrienza@pattonboggs.com)

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  
5100 Paint Branch Parkway (HFS-820)  
College Park, MD 20740

Re: Your July 12 Letter and Redactions for NDI Notification

Dear Ms. Satchell:

I am responding to your letter concerning the Notification sent on behalf of Chemi Nutraceuticals, Inc. for the new dietary ingredient IronAid™ (Iron Protein Succinylate). My client and I have carefully reviewed your letter and have the following comments. I note that the Notification had addressed on page 5 the issue of appropriate child proof packaging which you raise on page 2 of the letter: "Further, manufacturers must use child resistant closures and packaging where that total iron content per unit exceeds the allowable maximums as required under 21 C.F.R. § 111.50."

Chemi Nutraceuticals will ensure that all purchasers of IronAid™, i.e., manufacturers of dietary supplements containing it, will be given a copy of your July 12 letter and thus will be made aware of the need to label the finished product to: 1) limit the daily dosage to an amount that will not exceed the UL for iron when combined with food intake; and 2) include casein in the ingredient list and identify it as a milk protein, so that persons with milk allergies may avoid the product.

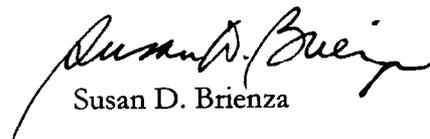
Chemi Nutraceuticals requests that certain material of a confidential and proprietary nature be redacted before its Notification is posted on the FDA's public docket. This material, which includes trade secrets as to exactly how IronAid™ is processed and manufactured, should not be disclosed to the public. The portions to be redacted are indicated on the two attached pages with strike-overs and cross-hatchings; this includes the redaction of Figure 1 in its entirety.

**PATTON BOGGS LLP**  
ATTORNEYS AT LAW

Felicia B. Satchell  
July 19, 2002  
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Thank you for your consideration in the matter of redactions.

Sincerely,

  
Susan D. Brienza

SDB:pah

Enclosure

cc: Mr. Scott Hagerman

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# **IronAid™ Iron Protein Succinylate (IPS)**

## **Introduction and Background on the Ingredient**

This New Dietary Ingredient Notification is submitted pursuant to 21 C.F.R. § 190.6 and Section 8 of the Dietary Supplement Health and Education Act. This Notification concerns the new dietary ingredient IronAid™ Iron Protein Succinylate ("IPS" or "IronAid™"). IPS is manufactured by Italfarmaco Spa of Italy, which is represented by its subsidiary Chemi Nutraceuticals, Inc. ("Chemi Nutra") in the U.S.

Chemi Nutra will not sell IPS directly to consumers, as a finished supplement product nor as an ingredient in a finished product, but rather will sell it to manufacturers and marketers of dietary supplements, in bulk, for inclusion as a dietary ingredient in a dietary supplement. IronAid™ is a raw material (ingredient), which will be marketed to the nutritional products industry, for use in dietary supplements. In form, IronAid™ is a reddish-brown colored, free-flowing powder.

IPS, to be used for iron supplementation, is a form of iron that is easy to digest. Iron deficiency anemia is a significant problem among certain high-risk populations. This is exacerbated by the fact that iron supplementation is often poorly tolerated due to gastric upset as well as by the poor absorption of those products designed to minimize gastric intolerance. IPS exhibits pH-dependent solubility designed specifically to overcome gastric tolerance and absorption problems. Specifically, IPS is insoluble at gastric pH, and soluble at intestinal pH, which helps prevent the iron gastric intolerance associated with iron supplementation while maintaining superior absorption.

Pharmacological studies also show that IPS does not bypass the transfer system of the intestinal mucosa that regulates iron uptake by blocking iron



# CHEMI Nutraceuticals

April 23, 2002

Ms. Karen Strauss  
Center for Food Safety and Applied Nutrition  
Project No. 79418  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

Re: Attachments For NDI Notification For IronAid™

Dear Ms. Strauss,

In response to your telephone correspondence with Susan Brienza, of Patton Boggs LLP, our legal counsel who is working with us on our NDI Notification for IronAid™, please find enclosed the following:

- Three (3) complete copies of the English translation of reference No. 1: Pagella, P.G., *Pharmacological and Toxicological Studies on an Iron Succinyl-Protein Complex (ITF282) for Oral Treatment of Iron Deficiency Anemia.*
- Three (3) complete copies of the English translation of reference No. 3: Biagi, G.L., *Pharmatotoxicological Report on Ferrolat (Iron Protein Succinylate)*. [English translation: Biagi, G.L., Medicinal Product: ITF 282. Part III. Toxicological And Pharmacological Documentation. *Ferrolat 40 – drinkable ampoules – Chronic toxicity studies in rats and mini-pigs and tolerability study (general pharmacological effects).*]
- Three (3) complete copies of the English translation of reference No. 4: Italfarmaco, *Scientific Profile on Iron Proteinsuccinylate (IPS)*, p. 10.
- Three (3) complete copies of the English translation of reference No. 10: Monaco, M., *Ferrolat: Ames test, Test for forward mutation in S. pombe P1 and test for mitotic gene conversion in S. cerevisiae D4*. [English translation: Monaco, M., Medicinal Product: ITF 282. Part III. Toxicological And Pharmacological Documentation. *Product: Ferrolat. Ames test – Forward mutation test in S. pombe – Mitotic gene conversion in S. cerevisiae.*]
- Three (3) complete copies of the English translation of reference No. 11: Mosesso, P., *Evaluation of the clastogenic action of Ferrolat on mouse bone marrow erythrocytes in vivo in the micronucleus*. [English translation: Mosesso, P., Medicinal Product: ITF 282. Part III. Toxicological And Pharmacological Documentation. *Evaluation of the clastogenic (chromosome-breaking) action of the substance Ferrolat on mouse bone marrow erythrocytes in vivo, in the micronucleous test.*]

I apologize for any inconvenience that this substitution of attachments has caused, and trust that your review process will continue in a straightforward and timely manner.

Sincerely,

  
Scott Hagerman  
President

Encl.

CC: Susan Brienza Esq., Patton Boggs LLP (w/out enclosure)

Bertha, 4-29-02  
Please Stamp + Log  
in today, The project  
date is on letter - will  
have a new 15-day  
date Thx Karen

Chemi Nutraceuticals, Inc.

4463 White Bear Parkway • Suite 105 • White Bear Lake, MN 55110  
Phone 651.407.0400 • Fax 651.407.0509