



Memorandum

OCT 2 1995

From Director, Division of Programs and Enforcement Policy, Office of Special Nutritionals,
HFS-455

Subject 75-Day Premarket Notification

To Dockets Management Branch, HFA-305

Product: PS-30
Firm: Foodsmith Corp., Crete, NE
Date received in FDA: July 10, 1995
90 day date: October 8, 1995

In accordance with the requirements of Section 413(a)(2) of the Federal Food, Drug and Cosmetic Act, the attached 75-day notification (which has been redacted to remove matters in the information that are trade secret or otherwise confidential, commercial information) should be placed on public display in Docket 95S-0316 after October 8, 1995.

Linda S. Kahl, Ph.D.

Attachment

95 OCT -3 AM 10:49
DOCKETS MANAGEMENT BRANCH

95S-0316

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FOODSMITH CORP.

Crete Office
1108 Ivy Avenue
Crete, NE
68333
402 826 3279

Lincoln Office
P.O. Box 83001
Lincoln, NE
68501
402 435 4154

1 July 95

Office of the Director
Center for Food Safety and Applied Nutrition
FOOD & DRUG ADMINISTRATION
Washington, DC 20204

Re: Office of Dietary Supplements and Notice of Intent to Sell New Product

Dear Director,

According to the Dietary Supplement Health and Education Act of 1994 (108 STAT. 4325) Foodsmith Corporation (Nebraska) must notify the FDA of its intent to manufacture and distribute for sale any new dietary supplement. A 75 day waiting period is granted to the FDA according to the Act.

Foodsmith Corporation intends to sell its protoprotein nutraceutical Lab #PS-30
sometime after the 75 day waiting period.

All suppliers use GMP and the mixers, packager and
warehousing are FDA approved.

Over 3000 servings of #PS-30 has been consumed by individuals both male & female and various ages. Only "improved wellness" or "no effect" has been noted. We have not run across any adverse effects. We advocate consumption by individual appetite and this has been very successful.

Thank you and we will continue to keep you advised.

Sincerely,


Philip C. Anderson
President
FOODSMITH CORP.
Crete

PCA/pba

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RECEIVED BY THE
OFFICE OF SPECIAL
NUTRITION AFFAIRS-450