



JUL 10 2000

Memorandum

Date

5627 '00 JUL 13 09:43

From

(Acting) Division Director, Division of Standards and Labeling Regulations, Office of  
Nutritional Products, Labeling and Dietary Supplements, HFS-820

Subject

75-Day Premarket Notification for New Dietary Ingredients

To

Dockets Management Branch, HFA-305

New Dietary Ingredient:

Ellaginol

Firm:

AUDAX, inc. Pharmaceuticals

Date Received by FDA:

April 27, 2000

90-Day Date:

July 25, 2000

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and  
Cosmetic Act, the attached 75-day premarket notification for the aftermentioned new  
dietary ingredient should be placed on public display in docket number 95S-0316 after  
July 25, 2000.

*Felicia B. Satchell*  
Felicia Satchell

95S-0316

RPT 72

JUL 10 2000

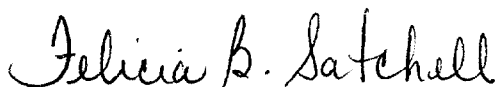
Charles E. Day, Ph.D.  
AUDAX inc. Pharmaceuticals  
1434 Sunbeam Road  
Leitchfield, Kentucky 42754

Dear Dr. Day:

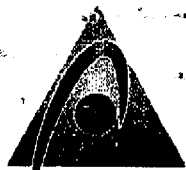
This is to notify you that your submission pursuant to section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) dated April 17, 2000, concerning the marketing of a substance that you assert is a new dietary ingredient (i.e., Ellaginol) was received by the Food and Drug Administration (FDA) on April 27, 2000. Your submission will be kept confidential for 90 days from the date of receipt, and after July 25, 2000, your submission will be placed on public display at Dockets Management Branch (Docket No. 95S-0316). Commercial and confidential information in the notification will not be made available to the public.

Please contact us if you have any questions concerning this matter.

Sincerely yours,



(Acting) Division Director  
Division of Standards  
and Labeling Regulations  
Office of Nutritional Products, Labeling  
and Dietary Supplements



**AUDAX inc.**  
**PHARMACEUTICALS**

*Helping People Live Longer, Healthier*

July 7, 2000

Dr. Roslyn Powers  
Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 "C" Street SW  
Washington, DC 20204

*rec'd  
7/7/00  
RFP  
HBM*

Dear Dr. Powers:

Thank you for your reply and helpful examples of further information needed regarding Ellaginol. Listed below are the dosage forms and conditions for use as per labeling in a format which is, hopefully, appropriate.

Dosage forms:

1. A tablet containing 10 mg of ellagic acid in the form of Ellaginol.
2. A capsule containing 10 mg of ellagic acid in the form of Ellaginol.
3. An admixture containing 10 mg of ellagic acid in the form of Ellaginol.
4. A liquid suspension containing 10 mg of ellagic acid in the form of Ellaginol.

Condition of use as per labeling:

1. Take 1 to 2 tablets once per day.
2. Take 1 to 2 capsules once per day.
3. Take one dose admixture 1 to 2 times per day.
4. Take one dose liquid suspension 1 to 2 times per day.

Please let me know if you require any further information. Thank you for your response.

Sincerely,

Charles E. Day, Ph.D.



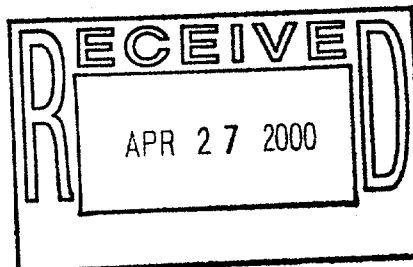
**AUDAX inc.**  
**PHARMACEUTICALS**

Helping People Live Longer, Healthier

70494

April 17, 2000

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street SW  
Washington, DC 20204



To Whom it May Concern:

Pursuant to 21CFR, Part 190, Subpart B, Sec. 190.6 notification is hereby provided of a new dietary ingredient.

1. Name and complete address of distributor of the new dietary ingredient:

Audax, Inc.  
1434 Sunbeam Road  
Leitchfield, KY 42754  
USA

2. Name of the new dietary ingredient:

Ellaginol - pure red raspberry (*Rubus idaeus* L.) extract rich in ellagic acid

3. Description of dietary supplements that contain new dietary ingredient:

*i.* Level of new dietary ingredient in dietary supplement:

200 mg Ellaginol per recommended dose of dietary supplement, equivalent to 10 mg ellagic acid per recommended dose of dietary supplement.

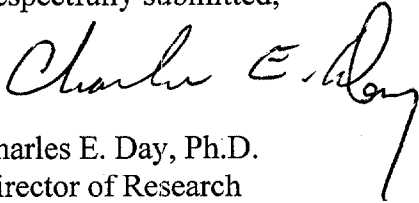
*ii.* Ordinary conditions of use of the supplement:

Recommended as a plant polyphenol dietary supplement

4. History of use and evidence of safety:

Red raspberries are a widely and commonly consumed fruit either eaten raw or served in deserts such as pies, jellies, jams, ice creams, etc. They are a rich dietary source of the polyphenolic ellagic acid. (See Table 4 in attached reprint from the Journal of Food Composition and Analysis, Volume 2, pages 338-349, entitled "Extraction, Stability, and Quantitation of Ellagic Acid in Various Fruits and Nuts."). A one cup serving of fresh raspberries contains 25 mg of ellagic acid. The recommended dose of the new dietary ingredient Ellaginol pure red raspberry extract rich in ellagic acid contains 10 mg of ellagic acid, which is less than one half the amount contained in a cup of fresh raspberries.

Respectfully submitted,



Charles E. Day, Ph.D.  
Director of Research  
Audax, Inc.  
1434 Sunbeam Road  
Leitchfield, KY 42754

CED: rg

Enclosure: Reprint from Journal of Food Composition and Analysis, Volume 2, pages 338-349, entitled "Extraction, Stability, and Quantitation of Ellagic Acid in Various Fruits and Nuts."

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