



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

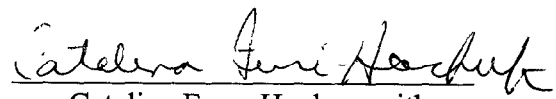
Memorandum

Date: November 22, 2002
From: Division of Standards and Labeling Regulations, Office of Nutritional Products,
Labeling and Dietary Supplements, HFS-822
Subject: 75-Day Premarket Notification of New Dietary Ingredients
To: Dockets Management Branch, HFA-305

0421 '03 JAN 27 P2

New Dietary Ingredient: Sheep Placenta
Firm: YAT CHAU (USA) INC.
Date Received by FDA: July 10, 2002
90-Day Date: October 8, 2002

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned new dietary ingredient should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.


Catalina Ferre-Hockensmith

Attachments

95S-0316

RPT 139



SEP 23 2002

Sherman Ye, Ph.D.
YAT CHAU (USA) INC.
131-37A, 41 Avenue, 1 Fl.
Flushing, New York 11355

Dear Dr. Ye:

This is in response to your letter to the Food and Drug Administration (FDA) dated July 6, 2002, making a submission for a new dietary ingredient pursuant to 21 U.S.C. 350b(a)(2) (section 413 of the Federal Food, Drug, and Cosmetic Act (the Act)) and 21 CFR 190.6. Your letter notified FDA of your intent to market a product containing sheep placenta, a substance that you assert is a new dietary ingredient.

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new 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 submission, and the agency has significant concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing sheep placenta will reasonably be expected to be safe. You state in your submission that "this dietary supplement has been in the United States food market for many years." However, your submission contains no information to support this statement nor that establishes that historical use, if any, is relevant to reaching a conclusion that your product, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. Your submission also

Page 2 – Dr. Ye

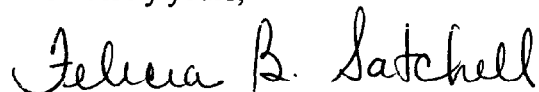
contains 14 references to articles published in the scientific literature. However, you did not provide copies of any of these studies as required by 21 CFR 190.6(b)(4). Further, the referenced studies do not appear to be relevant to an evaluation of the safety of sheep placenta used in a dietary supplement. The referenced studies appear only to address the physiological and pharmacological effects of substances found in sheep placenta in sheep or on cells *in vitro*, or in one instance, its use in obstetric practice in a traditional medicine setting. Such information is likely of limited utility in evaluating the safety of a dietary supplement containing sheep placenta.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that sheep placenta, when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your submission will be kept confidential for 90 days from the date of receipt, and after October 8, 2002, 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 questions concerning this matter.

Sincerely yours,



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



一洲美國藥業集團有限公司
YAT CHAU (USA) INC.

131-37A, 41 AVE., 1FL.
FLUSHING, NEW YORK 11355
U.S.A.

TEL : 1-800-238-3189 OR 1-800-864-1282
FAX : 1-888-332-7888 OR 1-718-886-9519
WEB: www.ycmart.com

July 6, 2002

Division of Standards and Labeling Regulations,
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-820)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD, 20740-3835

Re: Notification to the Secretary of Health and Human Services pursuant to Section 8(a)(2) of the Dietary Supplement Health and Education Act of October 25, 1994 (21 USC: Federal Food, Drug and Cosmetic Act). Marketing dietary ingredients under Supplement Health and Education Act.

To Whom It May Concern:

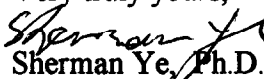
YAT CHAU (USA) INC. is requesting marketing clearance for its dietary supplement Placenta (Sheep). The premarket notification information required by FDA's Office of Special Nutritionals is as follows:

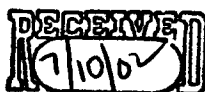
1. Classification name: Placenta (Sheep).
2. Classification: Dietary supplements and their ingredients are governed and regulated under the Dietary Supplement Health and Education Act. Pursuant to Section 8 of the Act such dietary supplements must reasonably be expected to be safe. **IN CONSIDERATION OF THE PROVISIONS OF THIS NEW LEGISLATION, YAT CHAU (USA) INC** desires to export and market Placenta (Sheep) in USA for use as a dietary supplements. This dietary supplement has been in the US food market for many years. It is reasonably expected to be safe. Please see label of product attached hereto as Attachment 1.
3. Label/Labeling/Advertisements: Draft copies of the package labeling and promotional material for the dietary supplement as well as a list of Scientific Publications are enclosed as Attachment 2.

We would appreciate your earliest attention to this submission. It is our understanding that upon the expiration of seventy six (76) days following your office's receipt of this notification and, absent any responsive commentary from your office, YAT CHAU will be able to market the dietary supplement in the United States.

Should you have any questions or comments regarding the enclosed information file, please do not hesitate to contact us.

Very truly yours,


Sherman Ye, Ph.D.





一洲美國藥業集團有限公司

YAT CHAU (USA) INC.

131-37A, 41 AVE., 1FL.
FLUSHING, NEW YORK 11355
U.S.A.

TEL : 1-800-238-3189 OR 1-800-864-1282
FAX : 1-888-332-7888 OR 1-718-886-9519
WEB: www.ycmarf.com

Supplement Facts

Serving Size: 2 Tablets

Amount Per 2 Tablets	% Daily Value
Placenta Extract	900mg *
Cholostrum	50mg *
Elatin	200mg *

* Daily Value Not Established

Other Ingredients: Gelatin,
Glycerin and Purified Water.



Yat Chau (USA) Inc.
Flushing, NY 11355

Lot: 15E18
Exp.: 01/23/2005

Suggested Serving: As a dietary supplement, take 2 tablets a day.

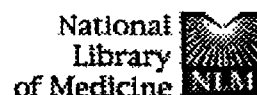
Warning: Keep out of the reach of children. Store at 15-30 °C (59-86 °F)

* This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.



Made in U.S.A.





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Entrez PubMed

- 1:** [Alvaro RE, Robertson M, Al-Saedi S, Lemke RP, Cates DB, Rigatto H.](#) **Related Articles**
 Preliminary characterization of a placental factor inhibiting breathing in fetal sheep.
 Reprod Fertil Dev. 1997;9(6):641-9.
 PMID: 9551669 [PubMed - indexed for MEDLINE]

PubMed Services

- 2:** [Charpigny G, Reinaud P, Tamby JP, Creminon C, Guillomot M.](#) **Related Articles**
 Cyclooxygenase-2 unlike cyclooxygenase-1 is highly expressed in ovine embryos during the implantation period.
 Biol Reprod. 1997 Nov;57(5):1032-40.
 PMID: 9369167 [PubMed - indexed for MEDLINE]

Related Resources

- 3:** [Tan W, Riggs KW, Thies RL, Rurak DW.](#) **Related Articles**
 Use of an automated fluorescent microsphere method to measure regional blood flow in the fetal lamb.
 Can J Physiol Pharmacol. 1997 Aug;75(8):959-68.
 PMID: 9360009 [PubMed - indexed for MEDLINE]

- 4:** [Amin JD, Wilsmore AJ.](#) **Related Articles**
 The effects of crude placental extract and erythritol on growth of Chlamydia psittaci (ovis) in McCoy cells.
 Vet Res Commun. 1997 Aug;21(6):431-5. No abstract available.
 PMID: 9266662 [PubMed - indexed for MEDLINE]

- 5:** [Onuaguluchi G, Ghasi S.](#) **Related Articles**
 The pharmacological basis for the use of dried sheep placenta in traditional obstetric practice in Nigeria.
 J Ethnopharmacol. 1996 Oct;54(1):27-36.
 PMID: 8941865 [PubMed - indexed for MEDLINE]

- 6:** [Alvaro RE, Rehan V, de Almeida V, Haider Z, Robertson M, Jansen A, Cates DB, Rigatto H.](#) **Related Articles**
 Specificity of a placental factor inhibiting breathing in fetal sheep.
 Reprod Fertil Dev. 1996;8(3):423-9.
 PMID: 8795106 [PubMed - indexed for MEDLINE]

- 7:** [al-Gubory KH, Machelon V, Nome F.](#) **Related Articles**
 Evidence that a non-steroidal factor from ovine placenta inhibits aromatase

activity of granulosa cells in vitro.
C R Acad Sci III. 1995 Jan;318(1):91-8.
PMID: 7757809 [PubMed - indexed for MEDLINE]

- 8:** Alvaro R, de Almeida V, al-Alaiyan S, Robertson M, Nowaczyk B, Cates D, Rigatto H. Related Articles

A placental extract inhibits breathing induced by umbilical cord occlusion in fetal sheep.

J Dev Physiol. 1993 Jan;19(1):23-8.
PMID: 8354849 [PubMed - indexed for MEDLINE]

- 9:** al-Gubory KH, Martinet J, Blanc MR, Poirier JC, Solari A. Related Articles

Evidence for a gonadal nonsteroidal factor that specifically inhibits release of luteinizing hormone in ewes.

J Reprod Fertil. 1992 Nov;96(2):509-19.
PMID: 1339831 [PubMed - indexed for MEDLINE]

- 10:** Barri M, Abbas SK, Pickard DW, Hammonds RG, Wood WI, Caple IW, Martin TJ, Care AD. Related Articles

Fetal magnesium homeostasis in the sheep.

Exp Physiol. 1990 Sep;75(5):681-8.
PMID: 1700914 [PubMed - indexed for MEDLINE]

- 11:** Rodda CP, Kubota M, Heath JA, Ebeling PR, Moseley JM, Care AD, Caple IW, Martin TJ. Related Articles

Evidence for a novel parathyroid hormone-related protein in fetal lamb parathyroid glands and sheep placenta: comparisons with a similar protein implicated in humoral hypercalcaemia of malignancy.

J Endocrinol. 1988 May;117(2):261-71.
PMID: 3379358 [PubMed - indexed for MEDLINE]

- 12:** Bobe P, Doric M, Kinsky RG, Voisin GA. Related Articles

Modulation of mouse anti-SRBC antibody response by placental extracts.

Cell Immunol. 1984 Dec;89(2):355-64.
PMID: 6542455 [PubMed - indexed for MEDLINE]

- 13:** Mitchell BF, Caro J, Cross J, Challis JR. Related Articles

Adrenocorticotrophic activity of an extract from sheep placental tissue at term.

Am J Obstet Gynecol. 1984 Sep 15;150(2):217-22.
PMID: 6089565 [PubMed - indexed for MEDLINE]

- 14:** Mihaly GW, Jones DB, Morgan DJ, Ching MS, Webster LK, Smallwood RA, Hardy KJ. Related Articles

Placental transfer and renal elimination of cimetidine in maternal and fetal sheep.

J Pharmacol Exp Ther. 1983 Nov;227(2):441-5.
PMID: 6631723 [PubMed - indexed for MEDLINE]

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