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Notice of FDA Action
Entry Number: AMG-0C40393-5

Notice Number: 3
Page: 2

Please provide documentation concerning all products in this entry to the FDA office below. Include the USCS document (eg. CF-3461 or CF-7501) and commercial invoice for these products, annotated to show the ACS/FDA line numbers sent electronically.

Also, advise FDA upon actual availability, and include date, location, and warehouse control number, where applicable, for all lines in this entry.

Daryl D. Javallana, Inspector
U.S. Food & Drug Administration
P.O. Box 59-2256
Miami, FL 33159-2256

(305) 526-2900
(305) 526-7483 (FAX)
DJAVELLA@ORA.FDA.GOV

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EXTENSION REQUEST GRANTED

LINE

<u>ACS/FDA</u>	<u>Product Description</u>	<u>Respond By</u>
001/001	PASTEURIZED CRABMEAT Reason: Importer searching for acceptable private labs to run Chloramphenicol analysis.	January 29, 2003

Carlos W. Hernandez, Investigator

(305) 526-2800ext. 41

This extension is granted until the dates shown above.

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Notice Prepared by: Carlos W. Hernandez
For the District Director, U.S. Food & Drug Administration

United States Food and Drug Administration
Florida District Office

Notice of FDA Action

Entry Number: AMG-0040393-5

Notice Number: 2
November 26, 2002

Filer:

Concept Brokerage Inc.
2402 NW 72 AVE.
MIAMI FL 33122

Attention : CONCEPT BR
Broker Box: 167

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Port of Entry: 5201, Miami, FL
Carrier : SL MERCURY
Date Received: November 8, 2002
Arrival Date : November 6, 2002

Importer of Record: John Keeler & Co Inc, Miami FL
Consignee: John Keeler & Co Inc, Miami FL 331781

HOLD DESIGNATED

Documents Required and Notify FDA of Availability

Summary of Current Status of Individual Lines

@ LINE

ACS/FDA	Product Description	Quantity	Current Status
* a 001/001	PASTEURIZED CRABMEAT	12720 LB	Detained 11-26-2002

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee id

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following USCS conditional release to a location within the local metropolitan area or to a location approved by the FDA office at the number below.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative

Please provide documentation concerning all products in this entry to the FDA

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Also, advise FDA upon actual availability, and include date, location, and warehouse control number, where applicable, for all lines in this entry.

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DETENTION

The following products are subject to refusal pursuant to the Federal Food Drug and Cosmetic Act (FD&CA), Public Health Service Act (PHSA), or other related acts in that they appear to be adulterated, misbranded or otherwise in violation as indicated below:

LINE

<u>ACS/FDA</u>	<u>Product Description</u>	<u>Respond By</u>
CG1/001	Product: PASTEURIZED CRABMEAT	

December 17, 2002

FD&CA Section 402(a)(2)(C)(ii); 801(a)(3); ADULTERATION

The article appears to contain a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 512. Product contains Chloramphenicol. You may refer to Import Alert 16-124 for guidance on detentions of future shipments from the same manufacturer.

You have the right to provide oral or written testimony, to the Food & Drug Administration, regarding the admissibility of the article(s) or the manner in which the article(s) can be brought into compliance. This testimony must be provided to FDA on or before the dates shown above.

Please direct your response to:
Carlos W. Hernandez, Investigator
U.S. Food & Drug Administration
P.O. Box 59-2256
Miami, FL 33159-2256

(305) 526-2800 ext. 41
(305) 526-2693 (FAX)
CHERNAND@ORA.FDA.GOV

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SAMPLES COLLECTED

LINE	Product Description	Est. Cost
001/001	PASTEURIZED CRABMEAT	\$ 66.09

Sample: 12 LB - Collected 12/ approx 1lb subs from 12 different ctns s/a/r
from 500 ctns of Jumbo lump.

Notice Prepared by: Carlos W. Hernandez
For the District Director, U.S. Food & Drug Administration