SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 230

General Rules and Regulations, Securities Act of 1933

CFR Correction

In Title 17 of the Code of Federal Regulations, Parts 200 to 239, revised as of April 1, 2010, on page 686, in § 230.501, following paragraph (e)(3), reinstate the Note to paragraph (e) to read as follows:

§ 230.501 Definitions and terms used in Regulation D.

* * * * *

(e) * * *

NOTE: The issuer must satisfy all the other provisions of Regulation D for all purchasers whether or not they are included in calculating the number of purchasers. Clients of an investment adviser or customers of a broker or dealer shall be considered the "purchasers" under Regulation D regardless of the amount of discretion given to the investment adviser or broker or dealer to act on behalf of the client or customer.

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DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

DEPARTMENT OF THE TREASURY

19 CFR Part 141

Entry of Merchandise

CFR Correction

In Title 19 of the Code of Federal Regulations, Parts 141 to 199, revised as of April 1, 2010, on page 6, the second general authority citation for part 141 is removed.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. FDA–1999–F–0056; Formerly Docket No. 1999F–4372]

Irradiation in the Production, Processing, and Handling of Food; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; denial of requests for a stay of effective date and for a hearing; response to objections; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is denying requests for a hearing on the final rule that amended the food additive regulations to provide for the safe use of ionizing radiation for the control of *Vibrio* species and other foodborne pathogens in fresh or frozen molluscan shellfish. After reviewing objections to the final rule and requests for a hearing, FDA has concluded that the objections do not justify a hearing or otherwise provide a basis for revoking the regulation. FDA also is denying the request for a stay of the effective date of the amendment to the food additive regulations.

DATES: The August 16, 2005, effective date for the final rule published at 70 FR 48057 is confirmed.

FOR FURTHER INFORMATION CONTACT: Lane A. Highbarger, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1204.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Objections, Requests for a Hearing, and Requests for a Stay
III. Standards for Granting a Hearing
IV. Analysis of Objections and Response to Hearing Requests
A. Studies on Animals Fed Clams
B. Microbiological Safety of Molluscan Shellfish
C. Reasonable Certainty of No Harm
D. Factors Unique to Molluscan Shellfish
E. Application of 100-Fold Safety Margin for 2-Alkylcyclobutanones
F. Alleged Rejection of Published Evidence
G. Alleged Warnings on Potential Risks
H. Alleged Failure to Follow Critical Guidelines for Food Additives
I. Wholesomeness
J. FDA Review Memoranda
K. Chemicals Formed in Irradiated Foods
V. Summary and Conclusion
VI. References

I. Introduction

FDA published a notice in the **Federal Register** of October 19, 1999 (64 FR 56351), announcing the filing of a food additive petition (FAP 9M4682) by the National Fisheries Institute and the Louisiana Department of Agriculture and Forestry. In the **Federal Register** of August 16, 2005 (70 FR 48057), FDA issued a final rule permitting the irradiation of fresh or frozen molluscan shellfish for the control of *Vibrio* spp. and other food-borne pathogens. FDA based its decision on data in the petition and in its files. In the preamble to the final rule, FDA outlined the basis for its decision and responded to questions raised in several comments from Public Citizen and the Center for Food Safety (PC/CFS). The preamble to the final rule advised that objections to the final rule and requests for a hearing were due within 30 days of the publication date (*i.e.,* by September 15, 2005).

II. Objections, Requests for a Hearing, and Requests for a Stay

Section 409(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(f)(1)) provides that, within 30 days after publication of an order relating to a food additive regulation, any person adversely affected by such order may file objections, specifying with particularity the provisions of the order "deemed objectionable, stating reasonable grounds therefore, and requesting a public hearing upon such objections."

Under part 171 (21 CFR part 171) in § 171.110 of the food additive regulations, objections and requests for a hearing are governed by part 12 (21 CFR part 12) of FDA's regulations. Under § 12.22(a), each objection must meet the following conditions: (1) Must be submitted on or before the 30th day after the date of publication of the final rule; (2) must be separately numbered; (3) must specify with particularity the provision of the regulation or proposed order objected to; (4) must specifically state each objection on which a hearing is requested; failure to request a hearing on an objection constitutes a waiver of the right to a hearing on that objection; and (5) must include a detailed description and analysis of the factual information to be presented in support of the objection if a hearing is requested; failure to include a description and analysis for an objection constitutes a waiver of the right to a hearing on that objection.

Following publication of the final rule permitting the irradiation of fresh or frozen molluscan shellfish for the