practice to offer for sale a misbranded textile fiber product or wool product. *See* 15 U.S.C. 70a and 68a. Textile fiber products and wool products are misbranded if they are not labeled as to the constituent fiber content, the percentages of fiber content or the name of the country where these products were processed or manufactured. *See* 15 U.S.C. 70b and 68b.

The Commission's proposed complaint further alleges that proposed respondents have sold wearing apparel to consumers after removing the care labels from these articles of clothing. The Commission's Trade Regulation Rule relating to the Care Labeling of Textile Wearing Apparel, *see* CFR part 423, requires manufacturers and importers to affix labels to articles of textile wearing apparel in order to provide regular care instructions to purchasers. The proposed complaint alleges that proposed respondents' removal of these care labels is an unfair and deceptive act or practice, in violation of section 5 of the Federal Trade Commission Act, 15 U.S.C. 45, because consumers are misled into using improper care procedures that are harmful to the articles of wearing apparel.

The proposed consent order is drafted to ensure proposed respondents' compliance with the relevant statutes and regulations by enjoining future violations. The proposed order prohibits proposed respondents from selling misbranded textile fiber products and wool products and from selling wearing apparel from which proposed respondents have removed the required care label. The proposed order also contains standard order provisions requiring proposed respondents to: Retain records demonstrating their compliance with the order; distribute the order to certain present and future employees; notify the Commission of any changes in the structure of the corporate respondent or in the business or employment of the individual respondent; and to report to the Commission their compliance with the terms of the order.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order to modify in anyway its terms.

C. Landis Plummer,

Acting Secretary.

[FR Doc. 92-17124 Filed 7-20-92; 12:01 pm]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control

Cooperative Research and Development Agreement; CRADA 92-03

AGENCY: Centers for Disease Control (CDC), Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The Centers for Disease Control (CDC), National Center for Environmental Health and Injury Control, Division of Environmental Health Laboratory Sciences, desires to enter into a Cooperative Research and Development Agreement (CRADA) with manufacturers of in vitro diagnostic products and/or instrumentation to develop and/or improve methodology for a reference method for the measurement of low density lipoprotein (LDL) cholesterol. The collaborator and CDC will jointly perform research aimed at the development or improvement of a method to achieve the specificity, precision, accuracy, and transferability required of a national reference method. The CDC will provide technical expertise, consultation and guidance, reference sera, analytical support, and method evaluation and testing.

It is anticipated that all inventions that may arise from this CRADA will be jointly owned and with an option for an exclusive royalty-bearing license to the collaborator with which the CRADA is made. The CRADA will be executed for a 2-year period with the possibility of renewal for another 2-year period.

Because CRADAs are designed to facilitate the development of scientific and technological knowledge into useful, marketable products, a great deal of latitude is given to Federal agencies in implementing collaborative research. As a Federal agency, the CDC may accept staff, facilities, equipment, supplies, and money from the other participants in a CRADA; CDC may provide staff, facilities, equipment, and supplies to the project. The single restriction in this exchange is that CDC may not provide funds to the other participants in a CRADA.

SUPPLEMENTARY INFORMATION: This opportunity is available until 30 days after publication of this notice. Respondents may be provided a longer period of time to furnish additional information if CDC finds this necessary. For additional information contact:

Technical Contact

Parvin P. Waymack, Ph.D., Special Activities Branch (404) 488-4126, or L. Omar Henderson, Ph.D., Clinical Biochemistry Branch (404) 488-4132 Division of Environmental Health Laboratory Sciences, National Center for Environmental Health and Injury Control, Centers for Disease Control, 1600 Clifton Road, NE., Mailstop F-25, Atlanta, GA 30333.

Business Contact

Jim Holler, Ph.D., Special Activities Branch, Division of Environmental Health Laboratory Sciences, National Center for Environmental Health and Injury Control, Centers for Disease Control, 1600 Clifton Road, NE., Mailstop F-25, Atlanta, GA 30333, telephone (404) 488-4176.

Applicants will be judged according to the following criteria:

1. Soundness of the methodological approach and research plan;
2. Adequacy and technical capabilities of the staff to develop the desired method;
3. Ability to develop, produce, market, and support the necessary reagent and instrumentation;
4. Evidence of scientific credibility; and
5. Ability to complete the CRADA in a timely fashion.

This CRADA is proposed and implemented under the 1986 Federal Technology Transfer Act: Public Law 99-502.

The responses must be made to: Jim Holler, Technology Transfer Coordinator, Division of Environmental Health Laboratory Sciences, NCEHIC, Centers for Disease Control; 1600 Clifton Road, NW., Mailstop F-25; Atlanta, GA 30333.

Dated: July 15, 1992.

Ladene H. Newton,

Acting Associate Director for Management and Operations; Centers for Disease Control.

[FR Doc. 92-17089 Filed 7-20-92; 12:01 pm]

BILLING CODE 4160-18-M

Cooperative Research and Development Agreement, CRADA 92-04

AGENCY: Centers for Disease Control (CDC), Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The Centers for Disease Control (CDC), National Center for Environmental Health and Injury Control, Division of Environmental Health Laboratory Sciences, desires to enter into a Cooperative Research and Development Agreement (CRADA) with manufacturers of control and reference materials to develop a stable

preparation (preferably lyophilized) suitable for standardizing the measurement of Apo B and low density lipoprotein (LDL) cholesterol. The collaborator and CDC will jointly perform research aimed at the development of a stable lyophilized reference material which is essentially matrix free and closely approximates fresh human serum in the measurement of Apo B and LDL-cholesterol. The CDC will provide technical expertise, consultation and guidance, analytical support, and evaluation and testing of the reference sera.

It is anticipated that all inventions that may arise from this CRADA will be jointly owned and with an option for an exclusive royalty-bearing license to the collaborator with which the CRADA is made. The CRADA will be executed for a 2-year period with the possibility of renewal for another 2-year period.

Because CRADAs are designed to facilitate the development of scientific and technological knowledge into useful, marketable products, a great deal of latitude is given to Federal agencies in implementing collaborative research. As a Federal agency, the CDC may accept staff, facilities, equipment, supplies, and money from the other participants in a CRADA; CDC may provide staff, facilities, equipment, and supplies to the project. The single restriction in this exchange is that CDC may not provide funds to the other participants in a CRADA.

SUPPLEMENTARY INFORMATION: This opportunity is available until 30 days after publication of this notice. Respondents may be provided a longer period of time to furnish additional information if CDC finds this necessary. For additional information contact:

Technical Contact

L. Omar Henderson, Ph.D., Clinical Biochemistry Branch (404) 488–4132 or Parvin P. Waymack, Ph.D., Special Activities Branch (404) 488–4126, Division of Environmental Health Laboratory Sciences, National Center for Environmental Health and Injury Control, Centers for Disease Control, 1600 Clifton Road, NE., Mailstop F–25, Atlanta, GA 30333.

Business Contact

Jim Holler, Ph.D., Special Activities Branch, Division of Environmental Health Laboratory Sciences, National Center for Environmental Health and Injury Control, Centers for Disease Control, 1600 Clifton Road, NE., Mailstop F–25, Atlanta, GA 30333, telephone (404) 488–4176.

Applicants will be judged according to the following criteria:

1. Soundness of the research plan and approach;
2. Adequacy and technical capabilities of the staff to develop the desired reference material;
3. Ability to maintain, store, distribute, and support the production of reproducible lots of reference material;
4. Evidence of scientific credibility; and
5. Ability to complete the CRADA in a timely fashion.

This CRADA is proposed and implemented under the 1986 Federal Technology Transfer Act: Public Law 99–502.

The responses must be made to: Jim Holler, Technology Transfer Coordinator, Division of Environmental Health Laboratory Sciences, NCEHIC, Centers for Disease Control, 1600 Clifton Road, NE., Mailstop F–25, Atlanta GA 30333.

Dated: July 15, 1992.

Ladene H. Newton,

Acting Associate Director for Management and Operations, Centers for Disease Control.

[FR Doc. 92–17090 Filed 7–20–92; 12:01 pm]

BILLING CODE 4160–18–M

Food and Drug Administration

[Docket No. 92F–0261]

Cardolite Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Cardolite Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 3-pentadecenyl phenol mixture (obtained from cashew nutshell liquid) reacted with formaldehyde and ethylenediamine in a ratio of 1:2:2 as an epoxy curing agent in resins and coatings intended for contact with food.

FOR FURTHER INFORMATION CONTACT: Helen R. Thorsheim, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9511.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 2B4326) has been filed by Cardolite Corp., c/o 1414 Fenwick Lane, Silver Spring, MD 20910. The petition proposes to amend the food additive regulations to provide for the safe use of 3-pentadecenyl phenol mixture (obtained from cashew nutshell liquid) reacted with formaldehyde and ethylenediamine in a ratio of 1:2:2 as an epoxy curing agent in resins and coatings intended for contact with food.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: July 8, 1992.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 92–17060 Filed 7–20–92; 12:01 pm]

BILLING CODE 4160–01–F

[Docket No. 91P–0335]

Canned Tuna Deviating From Identity Standard; Amendment of Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is amending a temporary permit, issued to Bumble Bee Seafoods, Inc., to market test products designated as "chunk light tuna with jalapeno in water" and "chunk light tuna with jalapeno in oil" that deviate from the U.S. standards of identity for canned tuna (21 CFR 161.190), to increase the area of distribution, and to increase the amount of chunk light tuna with jalapeno in oil to be distributed.

FOR FURTHER INFORMATION CONTACT: Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFF–414), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5106.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17, FDA issued a temporary permit (56 FR 48212, September 24, 1991) to Bumble Bee Seafoods, Inc., 5775 Roscoe Ct., San Diego, CA 92123, to market test in interstate commerce canned tuna products formulated by adding chopped or diced jalapeno peppers that have been previously prepared and packed in brine. The agency issued the permit to facilitate market testing in the southwestern United States.

The test products deviate from the U.S. standard of identity for canned

tuna (21 CFR 161.190) in that they contain diced or chopped green jalapeno peppers. The amount of jalapeno peppers added does not exceed 10 percent of the water capacity of the can. Jalapeno peppers replace part of the liquid (water or oil) and do not affect the tuna fish fill portion. The test products meet all requirements of the standard with the exception of this deviation.

Bumble Bee Seafoods, Inc., has requested that FDA amend its temporary permit by increasing the area of distribution to include the entire United States and its territories and possessions. The firm also requested that FDA amend its temporary permit to increase the amount of chunk light tuna with jalapeno in oil from 300,000 cases containing 24 cans of tuna with jalapeno peppers in soybean oil, each can weighing 175 grams (6 1/8 ounces), to 400,000 cases. The amount of tuna with jalapeno peppers in spring water to be market tested remains the same. The purpose of the amendment is to provide the permit holder with a broader base for measuring consumer acceptance of the test products.

Therefore, under the provision of 21 CFR 130.17(f), FDA is amending the temporary permit to increase the area of distribution to include the entire United States and its territories and possessions and to increase the quantity of chunk light tuna with jalapeno in oil from 300,000 to 400,000 cases. All other terms and conditions of this permit remain the same.

Dated: July 8, 1992.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 92-17062 Filed 7-20-92; 12:01 pm]

BILLING CODE 4160-01-F

[Docket No. 92F-0260]

Quantum Chemical Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Quantum Chemical Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of propylene modified ethylene-*n*-butyl acrylate for use as a component in the manufacture of food packaging materials.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9500.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 2B4327) has been filed by Quantum Chemical Corp., 11500 Northlake Dr., Cincinnati, OH 45249. The petition proposes to amend the food additive regulations to provide for the safe use of propylene modified ethylene-*n*-butyl acrylate for use as a component in the manufacture of food packaging materials.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: July 8, 1992.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 92-17061 Filed 7-20-92; 12:01 pm]

BILLING CODE 4160-01-F

[Docket No. 92E-0154]

Determination of Regulatory Review Period for Purposes of Patent Extension; ADSOL® Red Cell Preservation Solution System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ADSOL® Red Cell Preservation Solution System and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joel P. Sparks, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product ADSOL® Red Cell Preservation Solution System. ADSOL® Red Cell Preservation Solution System (sodium citrate, citric acid, dextrose, monobasic phosphate, mannitol, and adenine in BTHC plastic blood bags) is indicated for the collection and storage of blood and components under conditions equivalent to those employed with currently approved plastic containers. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ADSOL® Red Cell Preservation Solution System (U.S. Patent No. 4,710,532) from Morflex, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated May 6, 1992, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ADSOL® Red Cell Preservation