when appropriate, and other forms of information technology.

Telephone Questionnaire Administration to Control Subjects Recruited into FDA Lyme Vaccine Safety Study, ''A Case-Control Study of HLA Type and T-Cell Reactivity to Recombinant Outer Surface Protein A and Human Leukocyte Function-Associated Antigen-1''

Section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355), requires that important safety information relating to all human prescription drug products be made available to FDA so that it can take appropriate action to protect the public health when necessary. Section 702 of the act (21 U.S.C. 372) authorizes investigational powers to FDA for enforcement of the act.

Under section 519 of the act (U.S.C. 360i), FDA is authorized to require manufacturers to report medical device-related deaths, serious injuries, and malfunctions to FDA and to require user facilities to report device-related deaths directly to FDA and to manufacturers, and to report serious injuries to the manufacturer. Section 522 of the act (21 U.S.C. 360l) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health or gross deception of the consumer. Section 903(d)(2) of the act (21 U.S.C. 393(d)(2)) authorizes the Commissioner of Food and Drugs (the Commissioner) to implement general powers (including conducting research) to carry out effectively the mission of FDA. These sections of the act enable FDA to enhance consumer protection from risks associated with medical products usage that are not foreseen or apparent during the premarket notification and review process.

FDA's regulations governing application for agency approval to market a new drug (21 CFR part 314) and regulations governing biological products (21 CFR part 600) implement these statutory provisions.

Currently FDA monitors medical product related postmarket adverse events via both the mandatory and voluntary MedWatch reporting systems using FDA forms 3500 and 3500A (OMB control number 0910–0291) and the vaccine adverse event reporting system (VAERS) using form VAERS–1. Health care providers and manufacturers are required by law (42 U.S.C. 300aa–25) to report adverse events following vaccination listed in the vaccine injury table. Reports for reactions to other vaccines are voluntary, and are received from vaccine recipients, their health care providers, and other reporters.

FDA is seeking OMB clearance to collect vital information through the use of the proposed survey questionnaire for control subjects participating in this vaccine safety study. The intended respondents are control subjects previously recruited to participate in this study, and are matched with case subjects reported to VAERS who developed arthritis following Lyme vaccine administration. Informed consent for administration of this questionnaire will have been received prior to the interview, and the interview is to be conducted at a time specified by the control subject at the time of initial recruitment into this study. Case and control subjects should have similar age, gender, and ethnic backgrounds. Specific genetic and immune factors will be compared between case and control subjects. This is a common, accepted type of epidemiological study called a case-control study. Information collected includes medical and vaccination history, family history, and possible exposures such as in the workplace that may play a part in the development of arthritis in some patients. FDA will use the information gathered from the use of this survey questionnaire to ensure appropriate matching of cases and controls in the study and to assess possible factors which may factor in the development of this adverse event. This study was approved by the FDA Research Involving Human Subjects Committee on February 15, 2002 (RIHSC #01–028B). This survey questionnaire is an abbreviated version of one used during enhanced surveillance followup of adverse events following Lyme vaccine administration reported to VAERS. The use of the vital information gathered using this survey questionnaire will aid FDA in assessing risks that may be associated with vaccine product usage that are not foreseen or apparent during the premarket notification and review process, so the agency may take appropriate public health or regulatory action including dissemination of this information as necessary and appropriate.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
''A Case-Control Study of HLA Type and T-Cell Reactivity to Recombinant Outer Surface Protein A and Human Leukocyte Function-Associated Antigen-1''	225	1	225	0.5	112.5

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA projects that there will be up to 75 case subjects recruited into this study with 3 control subjects recruited for each case subject, with a total maximum of 225 survey questionnaire respondents. FDA also projects a response time no greater than 0.5 hours per response. This estimate is based on previous results experienced with the instrument during enhanced surveillance followup of adverse events reported to VAERS. Respondents will only be contacted once during conduct of this study for the purposes of collection of vital information using this survey questionnaire.

Dated: June 21, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–16294 Filed 6–26–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02F–0142]

Cyanotech Corp.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 2A4732) proposing that the food additive regulations be amended to provide for the safe use of *Haematococcus* algae astaxanthin as a nutrient supplement.

FOR FURTHER INFORMATION CONTACT: James C. Wallwork, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202–418–3078.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of April 11, 2002 (67 FR 17700), FDA announced that a food additive petition (FAP 2A4732) had been filed by Cyanotech Corp., c/o T. Todd Lorenz, 11034 West Ocean Air Dr., ı 252, San Diego, CA 92130 (currently 73–4460 Queen Kaahumanu Hwy., ı 102, Kailua-Kona, HI 96740). The petition proposed to amend the food additive regulations in Part 172 *Food Additives Permitted for Direct Addition to Food for Human Consumption* (21 CFR part 172) to provide for the safe use of *Haematococcus* algae astaxanthin as a nutrient supplement. Cyanotech Corp. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7(a)).

Dated: June 3, 2002.

Laura M. Tarantino,

Deputy Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 02–16162 Filed 6–26–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0178]

Canned Tomatoes Deviating From Identity Standard; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a temporary permit has been issued to Del Monte Corp. to market test canned tomato products that deviate from the U.S. standard of identity for canned tomatoes. The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the products, identify mass production problems, and assess commercial feasibility, in support of a petition to amend the standard of identity for canned tomatoes.

DATES: This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but not later than September 25, 2002.

FOR FURTHER INFORMATION CONTACT: Ritu Nalubola, Center for Food Safety and Applied Nutrition (HFS–822), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), FDA is giving notice that a temporary permit has been issued to Del Monte Corp., One Market @ The Landmark, P.O. Box 193575, San Francisco, CA 94119–3575.

The permit covers limited interstate marketing tests of products identified as ''Stewed Tomatoes, Original Recipe,'' ''Chunky Tomatoes, Pasta Style,'' ''Diced Tomatoes, basil, garlic & oregano,'' ''Diced Tomatoes, garlic & onion,'' ''Diced Tomatoes, green pepper & onion,'' ''Tomato Wedges,'' ''Zesty Chunky Tomatoes, Chili Style,'' ''Stewed Tomatoes, Cajun Recipe with pepper, garlic, and Cajun spices,'' ''Stewed Tomatoes, Italian Recipe with basil, garlic & oregano,'' ''Stewed Tomatoes, Mexican Recipe with garlic, cumin, and jalapeños'' and ''Stewed Tomatoes, no salt added.'' These canned tomato products may deviate from the U.S. standard of identity for canned tomatoes (21 CFR 155.190) in two ways. First, a liquid carbohydrate sweetener, either corn syrup or high fructose corn syrup, is used as an optional ingredient in lieu of dry nutritive carbohydrate sweeteners. The liquid carbohydrate sweetener, corn syrup or high fructose corn syrup, is used in a quantity reasonably necessary to compensate for the tartness resulting from added organic acids, except that such addition of the liquid sweetener, in no case, may result in a finished canned tomato product with a tomato soluble solids content of less than 5.0 percent by weight as defined in 21 CFR 155.3(e) (which accounts for any added salt) and accounting for the soluble solids of the liquid sweetener. The feasibility of this tomato soluble solids requirement will be assessed during the temporary marketing of the test products. Second, this temporary marketing permit provides for use of the term ''chunky'' in lieu of the styles (i.e., whole, sliced, diced, and wedges) required by the standard. Except for the use of a liquid sweetener and the use of the alternative term ''chunky'' on some products, the test products meet all the requirements of the standard. Because test preferences vary by area, along with social and environmental differences, the purpose of this permit is to test the product throughout the United States.

This permit provides for the temporary marketing of a total of 5.6 million cases (5 million pounds or 2.3 million kilograms in weight) of the above-mentioned canned tomato products. The test products will be manufactured by Del Monte Corp. at 10652 Jackson Ave., Hanford, CA 93230. The products will be distributed by Del Monte Corp. in the United States. The information panel of the labels will bear nutrition labeling in accordance with 21 CFR 101.9. Each of the ingredients used in the food must be declared on the labels as required by the applicable sections of 21 CFR part 101. This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but not later than September 25, 2002.

Dated: June 19, 2002.

Christine Taylor,

Dierector, Office Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition.

[FR Doc. 02–16164 Filed 6–26–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00P–1439]

Iceberg Water Deviating From Identity Standard; Extension of Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the extension of a temporary permit issued to Iceberg Industries Corp., to market test products designated as ''Borealis Iceberg Water,'' a name not otherwise permissible under the U.S. standard of identity for bottled water. The extension will allow the permit holder to continue to collect data on consumer acceptance of products while the agency takes action on a petition to amend the