7430(e); 18 U.S.C. 2510 *et seq.*; 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.*, 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 46 U.S.C. app. 466c; 50 U.S.C. app. 5; Sec. 901–911, Pub. L. 106–387; Sec. 221, Pub. L. 107–56; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 6, 2004, 69 FR 48763, 3 CFR, 2004 Comp., p. 284.

SUPPLEMENT NO. 1 TO PART 774—[AMENDED]

■ 2. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 3—Electronics, Export Control Classification Number (ECCN) 3A002 is amended by revising the ''items'' paragraph of the List of Items Controlled section, to read as follows:

3A002 General purpose electronic equipment, as follows (see List of Items Controlled).

* * * * *

List of Items Controlled

Unit: * * *

Related Controls: * * *

Related Definitions: * * *

Items:

a. Recording equipment, as follows, and specially designed test tape therefor:

a.1. Analog instrumentation magnetic tape recorders, including those permitting the recording of digital signals (*e.g.*, using a high density digital recording (HDDR) module), having any of the following:

a.1.a. A bandwidth exceeding 4 MHz per electronic channel or track;

a.1.b. A bandwidth exceeding 2 MHz per electronic channel or track and having more than 42 tracks; or

a.1.c. A time displacement (base) error, measured in accordance with applicable IRIG or EIA documents, of less than ''0.1 :s;

Note: Analog magnetic tape recorders specially designed for civilian video purposes are not considered to be instrumentation tape recorders.

a.2. Digital video magnetic tape recorders having a maximum digital interface transfer rate exceeding 360 Mbit/s;

Note: 3A002.a.2 does not control digital video magnetic tape recorders specially designed for television recording using a signal format, which may include a compressed signal format, standardized or recommended by the ITU, the IEC, the SMPTE, the EBU, the ETSI, or the IEEE for civil television applications.

a.3. Digital instrumentation magnetic tape data recorders employing helical scan techniques or fixed head techniques, having any of the following:

a.3.a. A maximum digital interface transfer rate exceeding 175 Mbit/s; or

a.3.b. Being ''space qualified'';

Note: 3A002.a.3 does not control analog magnetic tape recorders equipped with HDDR conversion electronics and configured to record only digital data.

a.4. Equipment, having a maximum digital interface transfer rate exceeding 175 Mbit/s, designed to convert digital video magnetic tape recorders for use as digital instrumentation data recorders;

a.5. Waveform digitizers and transient recorders having all of the following: N.B.: See also 3A292.

a.5.a. Digitizing rates equal to or more than 200 million samples per second and a resolution of 10 bits or more; and

a.5.b. A continuous throughput of 2 Gbit/s or more;

Technical Note: For those instruments with a parallel bus architecture, the continuous throughput rate is the highest word rate multiplied by the number of bits in a word. Continuous throughput is the fastest data rate the instrument can output to mass storage without the loss of any information while sustaining the sampling rate and analog-to-digital conversion.

a.6. Digital instrumentation data recorders, using magnetic disk storage technique, having all of the following:

a.6.a. Digitizing rate equal to or more than 100 million samples per second and a resolution of 8 bits or more; and

a.6.b. A continuous throughput of 1 Gbit/s or more;

b. ''Frequency synthesizer'' ''electronic assemblies'' having a ''frequency switching time'' from one selected frequency to another of less than 1 ms;

c. Radio frequency ''signal analyzers'', as follows:

c.1. ''Signal analyzers'' capable of analyzing any frequencies exceeding 31.8 GHz but not exceeding 37.5 Ghz and having a 3 dB resolution bandwidth (RBW) exceeding 10 MHz;

c.2. ''Signal analyzers'' capable of analyzing frequencies exceeding 43.5 Ghz;

c.3. ''Dynamic signal analyzers'' having a ''real-time bandwidth'' exceeding 500 kHz;

Note: 3A002.c.3 does not control those ''dynamic signal analyzers'' using only constant percentage bandwidth filters (also known as octave or fractional octave filters).

d. Frequency synthesized signal generators producing output frequencies, the accuracy and short term and long term stability of which are controlled, derived from or disciplined by the internal master frequency, and having any of the following:

d.1. A maximum synthesized frequency exceeding 31.8 GHz, but not exceeding 43.5 GHz and rated to generate a pulse duration of less than 100 ns;

d.2. A maximum synthesized frequency exceeding 43.5 GHz;

d.3. A ''frequency switching time'' from one selected frequency to another of less than 1 ms; or

d.4. A single sideband (SSB) phase noise better than $-(126 + 20 \log 10F - 20 \log 10f)$ in dBc/Hz, where F is the off-set from the operating frequency in Hz and f is the operating frequency in MHz;

Technical Note: For the purposes of 3A002.d.1., 'pulse duration' is defined as the time interval between the leading edge of the pulse achieving 90% of the peak and the trailing edge of the pulse achieving 10% of the peak.

Note: 3A002.d does not control equipment in which the output frequency is either produced by the addition or subtraction of two or more crystal oscillator frequencies, or by an addition or subtraction followed by a multiplication of the result.

e. Network analyzers with a maximum operating frequency exceeding 43.5 GHz;

f. Microwave test receivers having all of the following:

f.1. A maximum operating frequency exceeding 43.5 GHz; and

f.2. Being capable of measuring amplitude and phase simultaneously;

g. Atomic frequency standards having any of the following:

g.1. Long-term stability (aging) less (better) than $1 \times 10{-}11$/month; or

g.2. Being ''space qualified''.

Note: 3A002.g.1 does not control non-''space qualified'' rubidium standards.

Dated: July 21, 2005.

Eileen Albanese,

Director, Office of Exporter Services.

[FR Doc. 05–14745 Filed 7–25–05; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 2001C–0486] (formerly Docket No. 01C–0486)

Listing of Color Additives Exempt From Certification; Tomato Lycopene Extract and Tomato Lycopene Concentrate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of tomato lycopene extract and tomato lycopene concentrate as color additives in foods. This action is in response to a petition filed by LycoRed Natural Products Industries.

DATES: This rule is effective August 26, 2005; except as to any provisions that may be stayed by the filing of proper objections. Submit written or electronic objections and requests for a hearing by August 25, 2005. See section VIII of this document for information on the filing of objections. The Director of the Office of the **Federal Register** approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication in new 21 CFR 73.585 effective August 26, 2005.

ADDRESSES: You may submit written or electronic objections and requests for a hearing, identified by Docket No. 2001C–0486, by any of the following methods:

• Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

• Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

• E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2001C–0486 in the subject line of your e-mail message.

• FAX: 301–827–6870.

Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All objections received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting objections, see the ''Objections'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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, 301–436–1303.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of October 30, 2001 (66 FR 54773), FDA announced that a color additive petition (CAP 1C0273) had been filed by LycoRed Natural Products Industries, c/o TC Associates, Inc., P.O. Box 285, West Boxford, MA 01885 (current address, c/o Mark R. Kaster, suite 1500, 50 South Sixth St., Minneapolis, Minnesota 55402–1498). The petition proposed to amend the color additive regulations in part 73 (21 CFR part 73) to provide for the safe use of tomato lycopene extract to color foods generally. The petition included information on two forms of tomato lycopene extract that differ primarily in concentration. The agency is listing the less concentrated form as tomato lycopene extract and the more concentrated form as tomato lycopene concentrate.

II. Identity and Manufacturing

Tomato lycopene extract is a red to dark brown viscous oleoresin containing lycopene. Lycopene is the pigment responsible for the red color of tomatoes. Tomato lycopene extract is manufactured as follows: (1) Fresh, edible varieties of tomatoes are crushed and heated at 70 to 120° C, and then centrifuged to separate the pulp from the liquid portion; (2) the tomato pulp is extracted with ethyl acetate; and (3) ethyl acetate is evaporated from the extracts, resulting in tomato lycopene extract. Tomato lycopene extract manufactured by the petitioner contains not less than 5.5 percent lycopene, which comprises not less than 70 percent of total carotenoids. Tomato lycopene concentrate is a mixture of crystalline and amorphous powder prepared from tomato lycopene extract by removing most of the tomato lipids with ethyl acetate followed by evaporating the solvent. Tomato lycopene concentrate manufactured by the petitioner contains not less than 60 percent lycopene.

III. Safety Evaluation

Lycopene is a commonly consumed food ingredient present in fresh tomatoes and in tomato-containing foods. The intake of lycopene from the petitioned use of the color additives in foods is similar to that from the consumption of tomatoes and tomato-containing foods. The agency reviewed the results of toxicological studies submitted in the petition. Based on this review, the agency concludes that there was no treatment-related toxicity from lycopene. The agency also conducted a comprehensive literature search that found no evidence of any significant toxicological effects of lycopene when consumed by humans. To further assure the purity and safety of the subject color additives, the agency is specifying in new § 73.585 that tomato lycopene extract be obtained from fresh, edible varieties of tomato and is establishing specifications for both color additives.

IV. Conclusion

Based on the data in the petition and other relevant material, FDA concludes the following: (1) The petitioned use of tomato lycopene extract and tomato lycopene concentrate as color additives in foods is safe, (2) the additives will achieve their intended technical effects, and thus, (3) the additives are suitable for this use. The agency concludes that part 73 should be amended as set forth in this document. In addition, based upon the factors listed in § 71.20(b) (21 CFR 71.20(b)), the agency concludes that certification of tomato lycopene extract and tomato lycopene concentrate is not necessary for the protection of the public health.

V. Inspection of Documents

In accordance with § 71.15 (21 CFR 71.15), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 71.15, the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

VI. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for CAP 1C0273 (66 FR 54773, October 30, 2001). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

VII. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Objections

This rule is effective as shown in the **DATES** section of this document, except as to any provisions that may be stayed by the filing of proper objections. Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for

which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will publish notice of the objections that the agency has received or lack thereof in the **Federal Register**.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Incorporation by reference, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

■ 1. The authority citation for 21 CFR part 73 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

■ 2. Section 73.585 is added to subpart A to read as follows:

§ 73.585 Tomato lycopene extract; tomato lycopene concentrate.

(a) *Identity.* (1) The color additive tomato lycopene extract is a red to dark brown viscous oleoresin extracted with ethyl acetate from tomato pulp followed by removal of the solvent by evaporation. The pulp is produced from fresh, edible varieties of the tomato by removing the liquid. The main coloring component is lycopene.

(2) The color additive tomato lycopene concentrate is a powder prepared from tomato lycopene extract by removing most of the tomato lipids with ethyl acetate and then evaporating off the solvent.

(3) Color additive mixtures made with tomato lycopene extract or tomato lycopene concentrate may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring food.

(b) *Specifications.* (1) Tomato lycopene extract shall conform to the following specification: Lycopene, not less than 5.5 percent of oleoresin as determined by the method entitled ''Qualitative Analysis of Lycopene, Its Isomers and Other Carotenoids in Different Concentrations of Lyc-O-Mato® (Tomato Oleoresin) and in Tomato Pulp by High Performance Liquid Chromatography (HPLC),'' S.O.P. number : Lab/119/01, Revision 01, dated May 30, 2001, published by LycoRed Natural Products Industries, which is incorporated by reference, or an equivalent method. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of the method from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. You may inspect a copy at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*

(2) Tomato lycopene concentrate shall conform to the following specification: Lycopene, not less than 60 percent of oleoresin as determined by the method identified in paragraph (b)(1) of this section.

(c) *Uses and restrictions.* Tomato lycopene extract and tomato lycopene concentrate may be safely used for coloring foods generally in amounts consistent with good manufacturing practice, except that they may not be used to color foods for which standards of identity have been issued under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

Dated: July 15, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–14631 Filed 7–25–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Tiamulin Liquid Concentrate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for use of tiamulin concentrate solution to prepare medicated drinking water for the treatment of swine dysentery and swine pneumonia.

DATES: This rule is effective July 26, 2005.

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0223, e-mail: *daniel.benz@fda.gov*.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, filed ANADA 200–360 that provides for use of Tiamulin Liquid Concentrate to prepare medicated drinking water for the treatment of swine dysentery and swine pneumonia. Phoenix Scientific, Inc.'s Tiamulin Liquid Concentrate is approved as a generic copy of Boehringer Ingelheim Vetmedica, Inc.'s DENAGARD (tiamulin) Liquid Concentrate approved under NADA 140–916. The ANADA is approved as of June 24, 2005, and the regulations are amended in § 520.2456 (21 CFR 520.2456) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

The regulations are also amended in § 520.2456 to reflect a more recent genus name for the causative pathogen for swine dysentery. This action is being taken to improve the accuracy of the regulations.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.