the additional claim for use of said premix in feed for beef cattle was inadvertently not codified.

The codification of an approved supplemental NADA does not require reevaluation of the safety and effectiveness data on file for this NADA 12–491. The regulations are amended accordingly.

A freedom of information summary of safety and effectiveness data and information submitted to support approval of NADA 12–491 for presently approved uses of tylosin premixes, including use in beef cattle feed, previously submitted in accordance with Part 20 (21 CFR Part 20) and § 514.11 (21 CFR 514.11) may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The Bureau of Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(iii) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This action is governed by the provisions of 5 U.S.C. 556 and 557 and is therefore excluded from Executive Order 12291 by section 1(a)(1) of the Order.

List of Subjects in 21 CFR Part 558

Animal drugs; Animal feeds.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Part 558 is amended in § 558.625 by revising paragraph (b)(1) to read as follows:

§ 558.625 Tylosin.

* * * * *

(b) * * *

(1) To 000986: 10, 40, 100 grams per pound, paragraph (f)(1)(i) through (vi) of this section.

* * * * *

Effective date. This amendment is effective April 6, 1982.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).)

Dated: March 17, 1982.

Robert A. Baldwin,

Associate Director for Scientific Evaluation.

[FR Doc. 82–9036 Filed 4–5–82; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 884

[Docket No. 80M–0430]

Ovutime, Inc.; Reclassification of Viscometer for Cervical Mucus

AGENCY: The Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it issued an order in the form of a letter to a petitioner reclassifying the viscometer for cervical mucus form class III (premarket approval) into class I (general controls). FDA also is issuing a final regulation that codifies the reclassification of the device. The effect of reclassifying a device into class I is to require that the device meet only the general controls applicable to all devices. If the device had remained classified in class III, each manufacturer of the device would have been required to submit to FDA for its approval an application for premarket approval. FDA reclassified this device in response to a petition from Ovutime, Inc., Newton, MA 02158.

EFFECTIVE DATES: The reclassification was effective on February 26, 1981. This rule becomes effective May 6, 1982.

FOR FURTHER INFORMATION CONTACT: Lillian Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION: On February 1, 1980, Ovutime, Inc., Newton, MA 02158, submitted to FDA, under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)), a petition requesting that a new device with the brand name "Ovutime Tackiness Rheometer" be reclassified from class III into class I. The device was classified by statute into class III because it was not substantially equivalent to a device in commerical distribution before enactment of the Medical Device Amendments of 1976 (Pub. L. 94–295), see 21 U.S.C. 360c(f)(1). FDA referred the petition to the Obstetrics-Gynecology Device Section of the Obstetrics-Gynecology and Radiologic Devices Panel (the Section) for a recommendation. The Section, which named the device the "cervical mucus viscometer," recommended that the device be reclassified from class III into class I. The Section did not recommend that the device be exempted from certain requirements of section 510, 519, or 520(f) of the act, as provided in section 513(f)(2)(B)(ii) of the act.

The recommendation was based on the Section's belief that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. In a notice published in the Federal Register of November 28, 1980 (45 FR 79161), FDA announced the Section's recommendation and provided a period of 30 days for interested persons to submit to FDA written comments on the recommendation. No comments were received. FDA agreed with the Section's recommendation. In accordance with section 513(f)(2)(C)(i) of the act and 21 CFR 860.134(b)(6) of the regulations, FDA approved the petition and, by order in the form of a letter dated February 26, 1981 and sent to the petitioner, reclassifed the device from class III into class I without exemptions.

Accordingly, as required by 21 CFR 860.134(b)(7) of the regulations, FDA is announcing the reclassification of a generic type of device FDA calls a viscometer for cervical mucus from class III into class I without exemptions. In addition, FDA is issuing a final regulation that codifies the reclassification of the device. Publication of this rule has been delayed because of the need to coordinate classification regulations on new, reclassified devices with regulations on devices that were in commerical distribution before enactment of the Medical Device Amendments. FDA advises that any device it determines to be substantially equivalent to the viscometer for cervical mucus also has been reclassified from class III into class I without exemptions. Based upon additional findings of the Section, FDA advises that the viscometer for cervical mucus that has been reclassified into class I has been reclassified only insofar as it is marketed for use as an adjunct in the clinical evaluation of fertility dysfunction. The labeling of the device should include a disclaimer of its use for contraceptive purposes, because such uses are investigational. Further, the labeling should include a statement to caution the user concerning the concomitant use of hormone therapy.

After considering the economic consequences of approving this reclassification, FDA certifies that this final rule requires neither a regulatory impact analysis, as specified in Executive Order 12291, nor a regulatory flexibility analysis, as defined in the Regulatory Flexibility Act (Pub. L. 96–

354). Approval of this petition will not have a significant economic impact on a substantial number of small entities. The petitioner, and all future manufacturers of a viscometer for cervical mucus, will be relieved of the costs of complying with the premarket approval requirements in section 515 of the act. There are no off-setting costs that the petitioner or other manufacturers would incur from reclassification into class I. The magnitude of the economic savings from approval of this petition depends on the extent of premarket approval studies that the petitioner would have conducted and the number of future competitors satisfying the same requirements. Neither of these parameters can be reliably calculated to permit quantification of the economic savings.

List of Subjects in 21 CFR Part 884

Medical devices; Obstetrical and gynecological devices.

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), Part 884 is amended in Subpart B by adding new § 884.1040, to read as follows:

§ 884.1040 Viscometer for cervical mucus.

(a) *Identification.* A viscometer for cervical mucus is a device that is intended to measure the relative viscoelasticity of cervical mucus collected from a female patient. Measurements of relative viscoelasticity are intended for use as an adjunct in the clinical evaluation of a female with chronic infertility, to determine the time of ovulation and the penetrability of cervical mucus to motile sperm.

(b) *Classification.* Class I (general controls).

Effective dates. This reclassification was effective February 26, 1981. This rule becomes effective on May 6, 1982.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)))

Dated: March 24, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-9039 Filed 4-5-82; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF LABOR

Office of the Secretary

29 CFR Subtitle A and Ch. XVII

30 CFR Ch. I

Display of Office of Management and Budget Control Numbers for Recordkeeping Requirements

AGENCY: Office of the Secretary, Labor.

ACTION: Technical amendments and correction.

SUMMARY: This document amends certain Department of Labor regulations to include control numbers which the Department has obtained from OMB prior to February 17, 1982, at the places in the regulations where current information collection requirements are described. OMB control numbers for other recordkeeping requirements appeared in the December 29, 1981 (46 FR 62844), and January 5, 1982 (47 FR 145), issues of the Federal Register. This document also removes obsolete references to previous GAO and OMB approvals of information collection requirements.

EFFECTIVE DATE: April 6, 1982.

FOR FURTHER INFORMATION CONTACT: Paul Larson, Director, Office of Management Reports and Analysis, Directorate of Management Policy and Systems, Room S–5526, Frances Perkins Building, U.S. Department of Labor, 200 Constitution Avenue, NW, Washington, D.C. 20210, Telephone 202–523–6331.

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The information collection requirements contained in the regulatory sections listed below have been assigned the control numbers contained in the listing by the Office of Management and Budget under the provisions of the Paperwork Reduction Act of 1980 (Pub. L. 96–511).

Guide to Agency Abbreviation Code

BLS—Bureau of Labor Statistics
ESA—Employment Standards Administration
MSHA—Mine Safety and Health Administration
OSHA—Occupational Safety and Health Administration

Text of Amendments

The following corrections are made in the table appearing on page 145 of the Federal Register of January 5, 1982:

1. Under BLS, the citation reading "29 CFR 1904.2, 1904.4, and 1904.5" should read "29 CFR 1904.2, 1904.4, 1904.5 and 1904.6".

2. Under BLS, the citation reading "29 CFR 1904.5" should read "29 CFR 1904.15(b) and 1904.21".

3. Under ESA, the citation reading "29 CFR 4.6(b)(2)(1)" should read "29 CFR 4.6(b)(2) and 4.6(k)".

4. Under ESA, the entry reading "29 CFR 4.6(1)(i) * * * OMB No. 1215–0127" should not have appeared and is removed.

The following text of each paragraph cited in the second column of the table, add parenthetically the corresponding OMB number listed in the third column:

Agency	Regulatory citation	OMB No.
OSHA	29 CFR 1915.10(c)(1), 1916.10(c)(1), and 1917.10(c)(1).	1218–0052
	29 CFR 1926.550(a)(11)	1218–0054
	29 CFR 1910.68(e)(3)	1218–0055
	29 CFR 1910.252(c)(6)	1218–0056
	29 CFR 1910.268	1218–0057
	29 CFR 1910.421(b) (1)–(5), 1910.423(d)(i–iii), and 1910.440.	1218–0058
	29 CFR 1910.1007 thru 1910.1014(g)(2).	1218–0059
	29 CFR 1910.1016(g)(2)	1218–0060
	29 CFR 1910.1043(k)	1218–0061
	29 CFR 1926.400(h)(3)(vii)	1218–0062
	29 CFR 1926.803(b)(5)	1218–0063
	29 CFR 1910.1015(g)(2)	1218–0044
MSHA	30 CFR 75.200 and 75.200–5	1219–0004
	30 CFR 57.5–25	1219–0012
	30 CFR Parts 55, and 56, and 30 CFR 57.4–23.	1219–0013
	30 CFR 57.4–69	1219–0022
	30 CFR 75.1107–16	1219–0027
	30 CFR 77.1713	1219–0028
	30 CFR Parts 55 and 56, and 30 CFR 57.19–121.	1219–0029
	30 CFR 57.21–21	1219–0030
	30 CFR 57.21–35	1219–0031
	30 CFR 77.1906	1219–0032
	30 CFR 77.1901	1219–0033
	30 CFR 75.1400–4 and 77.1403	1219–0034
	30 CFR 55.3–53, 56.3–53 and 57.3–53.	1219–0035
	30 CFR 57.5–47	1219–0039
	30 CFR Part 45	1219–0043
	30 CFR 75.1714–3	1219–0044
	30 CFR 57.11–58	1219–0045
	30 CFR 57.11–53	1219–0046
	30 CFR 55.19–57, 56.19–57, and 57.19–57.	1219–0047, 1219–0048
	30 CFR 55.5–5, 56.5–5 and 57.5–5.	1219–0048
	30 CFR 75.159 and 77.106	1219–0049
	30 CFR 77.1110	1219–0050
	30 CFR 77.1101	1219–0051
	30 CFR 75.1704–2	1219–0052
	30 CFR 75.1100–3	1219–0053
	30 CFR 75.1101–23	1219–0054
	30 CFR 57.4–73	1219–0055
	30 CFR 55.13–15, 56.13–15, and 57.13–15.	1219–0056
	30 CFR 57.18–28	1219–0057
	30 CFR 57.4–74	1219–0058
	30 55.18–2, 56.18–2, and 57.18–2.	1219–0059
	30 CFR 57.5–37	1219–0061
	30 CFR 55.4–48, 56.4–48, and 57.4–48.	1219–0062
	30 CFR 55.13–30, 56.13–20, and 57.13–30.	1219–0063
	30 CFR 55.9–1, 56.9–1, and 30 CFR 57.9–1.	1219–0064
	30 CFR 75.512, 75.313–1, 75.812, 75.1805, 75.1001–1, 75.1003–2, 75.800–4, 75.900–4, and 75.1806.	1219–0067
	30 CFR 48.9 and 48.29	1219–0070
	30 CFR 75.305, 75.316, 75.309–4, 75.300–4, 75.306, and 75.303.	1219–0075

Signed at Washington, D.C. this 29th day of March, 1982.

Raymond J. Donovan,

Secretary of Labor.

[FR Doc. 82-9093 Filed 4-5-82; 8:45 am]

BILLING CODE 4510-23-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA Docket No. AH300g/IVA; A-3-FRL-2067-7]

Approval and Promulgation of Implementation Plans; Approval of Revisions to the Virginia State Implementation Plan

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: On July 13, 1981 and on August 10, 1981, the Commonwealth of Virginia submitted rules and regulations governing the State's automobile inspection and maintenance (I/M) program and mobile source emission standards for inclusion in its State Implementation Plan (SIP). These regulations will apply only to vehicles registered in the Northern Virginia ozone nonattainment area. EPA is today approving revisions as part of the Virginia SIP.

EFFECTIVE DATE: This action is effective on May 6, 1982.

ADDRESSES: Copies of the SIP revisions and the accompanying support documents are available for inspection during normal business hours at the following addresses:

U.S. Environmental Protection Agency, Air Programs & Energy Branch (3AW10), Curtis Building, 6th & Walnut Streets, Philadelphia, Pennsylvania 19106. Attn: Ms. Patricia Sheridan

Virginia State Air Pollution Control Board, Ninth Street Office Building, Room 801, Richmond, Virginia 23219. Attn: Mr. John M. Daniel, Jr.

Public Information Reference Unit, Room 2922, EPA Library, U.S. Environmental Protection Agency, 401 M. Street SW., (Waterside Mall), Washington, D.C. 20460

The Office of the Federal Register, 1100 L Street NW., Room 8401, Washington, D.C. 20408

FOR FURTHER INFORMATION CONTACT: Ms. Eileen M. Glen at the EPA, Region III address or telephone 215/597-8187.

SUPPLEMENTARY INFORMATION: Under section 172 of the Clean Air Act, nonattainment plans for major urban areas which require an extension beyond 1982 for attainment of a standard for ozone or carbon monoxide, are required to include a vehicle I/M program as an element of the 1979 SIP revision. Full implementation of that program, in accordance with EPA's established I/M policy, is required in all cases by December 31, 1982.

Virginia included I/M as an element in their 1979 SIP revision. EPA's evaluation of and action on the I/M portion of Virginia 1979 SIP revision is documented in 45 FR 55180 (August 19, 1980), 46 FR 22185 (April 16, 1981) and 46 FR 45628 (September 14, 1981).

On May 15, 1980, the Commonwealth submitted to EPA a schedule for the implementation of the I/M program in Northern Virginia. Approval of that schedule, as revised by an April 3, 1981 submittal (EPA Docket No. AH300a/b/eVA), is the subject of a separate EPA rulemaking action. Two of the increments of progress in that schedule pertain to the adoption of Administrative and Procedural Regulations, and Motor Vehicle Emission Standards. The proposed SIP revisions, which are the subject of today's Notice, satisfy these increments. The I/M program itself was implemented on December 11, 1981.

EPA published the 1982 SIP policy (part of which pertains to I/M programs) on January 22, 1981 (46 FR 7182). As discussed in that policy, States with areas that have I/M programs under development or operational as part of their 1979 SIP revisions, were required to submit only qualitative descriptions of the I/M program elements in the 1979 SIP submittal. The 1982 SIP revision to be submitted to EPA on or before July 1, 1982, must include, unless already submitted and approved as part of a previous SIP submittal, rules and regulations and all other I/M elements which could affect the ability of the I/M program to achieve the minimum emission reduction requirements. More specifically, the 1982 submittal must include the following critical elements: (1) Inspection test procedures; (2) emission standards; (3) inspection station licensing requirements; (4) emission analyzer specification and maintenance/calibration requirements; (5) recordkeeping and record submittal requirements; (6) quality control, audit, and surveillance procedures; (7) procedures to assure that non-complying vehicles are not operated on the public roads; (8) any other official program rules, regulations and procedures; (9) a public awareness plan; and (10) a mechanics training program, if additional emission reduction credits are being claimed for mechanics training.

EPA will determine the overall adequacy of the critical elements of each I/M program and, therefore, the approvability of the 1982 SIP by comparing those elements to established I/M policy. I/M program elements must be consistent with EPA policy or a demonstration must be made that the program elements are equivalent.

State or local governments that have I/M programs, but plan to increase the coverage and/or stringency of the programs in order to achieve greater reductions and to demonstrate earlier attainment of the standards, must submit the program modifications in legally enforceable form through the 1982 SIP revision process.

In the case of a partial submittal, EPA's action will be limited to the submitted program elements. Final action on the total I/M program must be reserved until all elements are submitted and reviewed in order to assure that the program satisfies the requirements of Part D of the Clean Air Act.

On July 13, 1981 and August 10, 1981, the Commonwealth submitted certain elements designed to satisfy, in part, the I/M requirements for the 1982 SIP revision. These elements were fully described in EPA's proposed rulemaking published on December 23, 1981 (46 FR 62298). At the time, EPA proposed approval of all those completed elements, namely, the inspection test procedures, the emission standards, the inspection station licensing procedures, the emission analyzer specifications and maintenance/calibration requirements, the procedures to assure that non-complying vehicles are not operated on the public roads, and the other program rules, regulations and procedures describing the geographic coverage area, the start-up date, and the classes and ages of subject vehicles as well as the provisions for reference stations. We also proposed approval of the regulations submitted by the Commonwealth on July 13, 1981 and August 10, 1981 which only partially satisfy the following elements: Recordkeeping and record submittal requirements; and the quality control, audit, and surveillance procedures. Additional information, as outlined in the Proposed Rulemaking, must be submitted before these elements will be fully satisfied.

Public Comments

As a result of the proposed rulemaking, EPA received only one comment, from the State of Connecticut,