or "anticipated" annual percentage yield earned on the first two monthly statements ...ied during the quarter. However, on the ...arterly statement the dividends earned figure must reflect the amount actually paid.

3. *Compounding frequency using the average daily balance method.* Any compounding frequency, including daily compounding, can be used when calculating dividends using the average daily balance method. (See comment 707.7(b), which does not require credit unions to compound or credit dividends at any particular frequency).

B. Special formula for use where periodic statement is sent more often than the period for which dividends are compounded.

1. *Statements triggered by Regulation E.* Credit unions may, but need not, use this formula to calculate the annual percentage yield earned for accounts that receive quarterly statements and that are subject to Regulation E's rule calling for monthly statements when an electronic fund transfer has occurred. They may do so even though no monthly statement was issued during a specific quarter. This formula must be used for accounts that compound and credit dividends quarterly and that receive monthly statements, triggered by Regulation E, which comply with the provisions of § 707.6.

2. *Days in compounding period.* Credit unions using the special annual percentage yield earned formula must use the actual number of days in the compounding period.

Appendix B to Part 707—Model Clauses and Sample Forms

1. *Modifications.* Credit unions that modify the model clauses will be deemed in compliance as long as they do not delete information required by TISA or regulation or rearrange the format so as to affect the substance or clarity of the disclosures.

2. *Format.* Credit unions may use inserts to a document (see Sample Form B–11) or fill-in blanks (see Sample Forms B–4 and B–5, which use double underlining to indicate terms that have been filled in) to show current rates, fees or other terms.

3. *Disclosures for opening accounts.* The sample forms illustrate the information that must be provided to a member when an account is opened, as required by § 707.4(a)(1). (See § 707.4(a)(2), which states the requirements for disclosing the annual percentage yield, the dividend rate, and the maturity of a term share account in responding to a member's request.)

4. *Compliance with Regulation E.* Credit unions may satisfy certain requirements under Part 707 with disclosures that meet the requirements of Regulation E. (See § 707.3(c).) The model clauses and sample forms do not give examples of disclosures that would be covered by both this regulation and Regulation E (such as disclosing the amount of a fee for ATM usage). Credit unions should consult appendix A to Regulation E for appropriate Regulation E model clauses.

5. *Duplicate disclosures.* If a requirement ...s as a minimum balance applies to more ...n one account term (to obtain a bonus and determine the annual percentage yield, for example), credit unions need not repeat the requirement for each term, as long as it is clear which terms the requirement applies to.

6. *Guide to model clauses.* In the model clauses, italicized words indicate the type of disclosure a credit union should insert in the space provided (for example, a credit union might insert "March 25, 1995" in the blank for "(*date*)" disclosure). Brackets and diagonals ("/") indicate a Credit unions must choose the alternative that describes its practice (for example, [daily balance/average daily balance]).

7. *Sample forms.* The sample forms (B–4 through B–11) serve a purpose different from the model clauses. They illustrate various ways of adapting the model clauses to specific accounts. The clauses shown relate only to the specific transactions described.

By order of the National Credit Union Administration Board on July 26, 1994.

Becky Baker,

Secretary of the Board.

[FR Doc. 94–18719 Filed 8–2–94; 8:45 am]

BILLING CODE 7535–01–V–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 330

[Docket No. 92N–0454]

RIN 0905–AA06

Labeling of Drug Products for Over-The-Counter Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its general labeling policy for over-the-counter (OTC) drug products that allows for the interchangeable use of certain words in labeling required by an OTC drug monograph. Examples of words already allowed include: "doctor" or "physician," "consult" or "ask," and "indications" or "uses." This proposal provides for an additional phrase ("Drug interaction precaution" or "Avoid mixing drugs" or "Do not mix drugs"). The agency is also requesting public comment on changing the wording of warnings from negative phraseology to a more positive approach (i.e., "Do not use more than 7 days" to "Use only 7 days").

DATES: Written comments by October 17, 1994; written comments on the agency's economic impact determination by October 17, 1994. The agency is proposing that any final rule that may issue based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5000.

SUPPLEMENTARY INFORMATION:

Background

In the **Federal Register** of April 5, 1993 (58 FR 17553), the agency proposed to amend its general labeling policy for over-the-counter (OTC) drug products to allow for the interchangeable use of certain words in the labeling required by an OTC drug monograph. The agency had previously proposed in a number of tentative final monographs and included in a number of final monographs a provision that the words "doctor" and "physician" may be used interchangeably in the labeling of OTC drug products. Instead of including this provision in each OTC drug monograph, the agency proposed to include such a provision in § 330.1 (21 CFR 330.1) as part of the general conditions under which an OTC drug is generally recognized as safe, effective, and not misbranded. The agency also proposed that, at manufacturers' discretion, the word "ask" could be substituted for the word "consult," which appears in the directions for many OTC drug monograph ingredients. Thus, the agency proposed that the phrases "consult a physician," "consult a doctor," "ask a physician," and "ask a doctor" could be used interchangeably. The agency invited comments and suggestions as to such other terms that could be used interchangeably, i.e., terms general in nature that appear in more than one OTC drug monograph. The comments received in response to the proposed rulemaking were favorable and suggested a number of additional terms that could be used interchangeably.

In a final rule published in the **Federal Register** of January 28, 1994 (59 FR 3998), the agency allowed the following terms to be used interchangeably: (1) "Ask" or "consult," (2) "assistance" or "help,"(3) "clean" or "cleanse," (4) "continue" or "persist," (5) "continues" or "persists," (6) "doctor" or "physician," (7) "indication" or "use," (8) "indications" or "uses," and (9) "lung" or "pulmonary." These terms are included in § 330.1(i).

The agency intends to continue to examine labeling required by OTC drug monographs to provide consumers more simplified and understandable information. This includes interchangeable terms, alternative phraseology, and possibly a new or different labeling format. At this time, the agency is proposing additional words or phrases that could be used interchangeably. The words "Drug interaction precaution" appear in a number of OTC drug monographs. See, for example, § 341.76(c)(4) (21 CFR 341.76(c)(4)) which states: "*Drug interaction precaution.* Do not use this product if you are presently taking a prescription drug for high blood pressure or depression, without first consulting a doctor." The agency believes the phrase "Avoid mixing drugs" or "Do not mix drugs" may be better understood by consumers than "Drug interaction precaution." Accordingly, the agency is proposing to amend § 330.1(i) to include these additional terms that may be used interchangeably in the labeling of OTC drug products.

Additionally, the agency is requesting comment from manufacturers and the public on whether it would be desirable to change negatively worded warnings to a more positive phraseology. For example, in the labeling of first aid antibiotic drug products in § 333.150(c)(1) (21 CFR 333.150(c)(1)), the warning "Do not use in the eyes or apply over large areas of the body," could be changed to read: "Avoid use in the eyes or over large areas of the body." Similarly, the warning in § 333.150(c)(2), which states: "Do not use longer than 1 week unless directed by a doctor," could be changed to read: "Use for only 1 week unless directed by a doctor."

Another example is the warnings in § 331.30(c)(4) (21 CFR 331.30(c)(4)), which states: "Do not use this product except under the advice and supervision of a physician if you have kidney disease," and in § 331.30(c)(5) (21 CFR 331.30 (c)(5)), which states: "Do not use this product except under the advice and supervision of a physician if you are on a sodium restricted diet." These warnings could be changed to read: "Use only with a physician's help if * * *," or "Use only with the help of a doctor if * * *."

The warning statements cited are only selected examples. There are many other similar statements in proposed and final OTC drug monographs. At this time, the agency seeks comments on the following specific questions:

(1) Should the terms "Drug interaction precaution," "Avoid mixing drugs," or "Do not mix drugs" be used interchangeably?

(2) Is a positive phraseology for some warnings a desirable labeling approach or should the more emphatic negative phraseology be retained as the only allowed language in warning statements?

(3) Will consumers pay more attention to "Do not use" language than to "Use only" language? Do repetitive terms such as "Do not use" lose their impact and become less important when read by consumers?

(4) Should negative warnings be used only for the most important advice?

(5) Is it essential that similar products have identical warning language or may the language vary and still be desirable provided the meaning is the same?

The agency seeks comments from manufacturers, health professionals, and consumers on these issues. Any party having any survey data on these labeling approaches should provide that information to the agency.

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and, thus, is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. If this proposed rule becomes a final rule, the labeling options could be implemented at very little cost by manufacturers at the next printing of labels, for those products for which the manufacturer chooses to make a change. Accordingly, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on the labeling of OTC drug products. Types of impact may include, but are not limited to, costs associated with relabeling. Comments regarding the impact of this rulemaking on OTC drug products should be accompanied by appropriate documentation. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before October 17, 1994, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Written comments on the agency's economic impact determination may be submitted on or before October 17, 1994. Three copies of all comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 330

Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 330 be amended as follows:

PART 330—OVER-THE-COUNTER (OTC) HUMAN DRUGS WHICH ARE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED

1. The authority citation for 21 CFR part 330 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. Section 330.1 is amended by redesignating paragraphs (i)(7), (i)(8), and (i)(9) as paragraphs (i)(8), (i)(9), and (i)(10), respectively, and by adding new paragraph (i)(7), to read as follows:

§ 330.1 General conditions for general recognition as safe, effective and not misbranded.

* * * * *

(i) * * *

(7) "Drug interaction precaution" or "Avoid mixing drugs" or "Do not mix drugs".

* * * * *

Dated: July 27, 1994.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–18925 Filed 8–2–94; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 51

[AD-FRL–5022–9]

Preparation, Adoption, and Submittal of State Implementation Plans; Test Method 205, Appendix M

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule and notice of public hearing.

SUMMARY: The purpose of this proposed rule is to add a test method which would be used to verify the performance and accuracy of gas dilution systems during a field test. The test method is entitled, "Verification of Gas Dilution Systems for Field Instrument Calibrations," and will be added to 40 CFR Part 51, Appendix M, as Test Method 205. This method will allow the facility greater flexibility while assuring the Administrator of the quality of the calibration of the field analyzers.

A public hearing will be held, if requested, to provide interested persons an opportunity for oral presentation of data, views, or arguments concerning the proposed rule.

DATES: *Comments.* Comments must be received on or before October 17, 1994.

Public Hearing. If anyone contacts EPA requesting to speak at a public hearing by August 24, 1994, a public hearing will be held September 19, 1994 beginning at 10:00 a.m. Persons interested in attending the hearing should call the contact mentioned under **ADDRESSES** to verify that a meeting will be held.

Request to Speak at Hearing. Persons wishing to present oral testimony must contact EPA by August 24, 1994.

ADDRESSES: *Comments.* Comments should be submitted (in duplicate if possible) to: Central Docket Section (LE–131), Attention: Docket Number A–93–36, U.S. Environmental Protection Agency, Room M–1500, First Floor, Waterside Mall, 401 M Street, S.W., Washington, D.C. 20460.

Public Hearing. If anyone contacts EPA requesting a public hearing, it will be held at EPA's Emission Measurement Laboratory, Research Triangle Park, North Carolina. Persons interested in attending the hearing or wishing to present oral testimony should notify Rima Dishakjian, Emission Measurement Branch, Technical Support Division (MD–19), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number (919) 541–0443.

Docket. Docket No. A–93–36, containing materials relevant to this rulemaking, is available for public inspection and copying between 8:00 a.m. and 4:00 p.m., Monday through Friday, at EPA's Air Docket Section, Room M–1500, First Floor, Waterside Mall, 401 M Street, S.W., Washington, D.C. 20460. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Rima Dishakjian or Anthony Wayne, Emission Measurement Branch (MD–19), Technical Support Division, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number (919) 541–0443.

SUPPLEMENTARY INFORMATION:

I. The Rulemaking

A. Summary of Proposed Changes

A verification procedure for gas dilution systems is being proposed. Gas dilution systems allow the user to dilute a high level certified gaseous standard to the concentration levels needed for multi-point calibration. The instrumental test methods in 40 CFR Part 60, Appendix A (e.g., Methods 3A, 6C, 7E, 10, 15, 16, 20, 25A, and 25B) require on-site, multi-point calibration using gases of known concentrations. An extensive field test can require the tester to transport dozens of high pressure gas cylinders to a test site. If a gas dilution system were available, the number of gas cylinders to be transported to the test site would be greatly reduced. This procedure provides a mechanism for the tester to avoid the cost and risk associated with transport of multiple gas cylinders, while also providing assurances to the on-site Administrator that the calibration gases produced by the gas dilution system will be precise and accurate.

B. Comments and Responses on Draft

The proposed method was published through the Emission Measurement Technical Information Center as Conditional Test Method 007 in April 1991. No technical comments have been submitted thus far. Several commenters suggested that the protocol be published in the CFR, thus resulting in this action.

II. Administrative Requirements

A. Public Hearing

A public hearing will be held, if requested, to discuss the proposed rulemaking in accordance with Section 307(d)(5) of the Clean Air Act. Persons wishing to make oral presentations should contact EPA at the address given in the **ADDRESSES** section of this preamble. Oral presentations will be limited to 15 minutes each. Any member of the public may file a written statement with EPA before, during, or within 30 days after the hearing. Written statements should be addressed to the Central Docket Section address given in the **ADDRESSES** section of this preamble.

A verbatim transcript of the hearing and written statements will be available for public inspection and copying during normal working hours at EPA's Central Docket Section in Washington, D.C. (see **ADDRESSES** section of this preamble).

B. Docket

The docket is an organized and complete file of all the information submitted to or otherwise considered by EPA in the development of this proposed rulemaking. The principal purposes of the docket are to: (1) allow interested parties to identify and locate documents so that they can effectively participate in the rulemaking process, and (2) serve as the record in case of judicial review except for interagency review materials [Section 307(d)(7)(A)].

C. Office of Management and Budget Review

It has been determined that this rule is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to OMB review.

D. Regulatory Flexibility Act Compliance

Pursuant to the provisions of 5 U.S.C. 605(b), I hereby certify that this attached rule, if promulgated, will not have a significant economic impact on a substantial number of small entities because no additional costs will be incurred.

This rule does not contain any information collection requirements subject to OMB review under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*

List of Subjects in 40 CFR Part 51

Environmental protection, Administrative practice and procedure, Air pollution control, Carbon monoxide,

Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, and Volatile organic compounds.

Dated: July 14, 1994.

Carol M. Browner,

Administrator.

EPA proposes to amend title 40, chapter I, part 51 of the Code of Federal Regulations as follows:

PART 51—[AMENDED]

1. The authority citation for part 51 continues to read as follows:

Authority: 42 U.S.C. 7410(a)(2), 7475(e), 7502 (a) and (b), 7503, 7601(a)(1) and 7620.

Appendix M—Recommended Test Methods for State Implementation Plans

2. Appendix M to part 51 is amended by adding Method 205 to read as follows:

Method 205—Verification of Gas Dilution Systems for Field Instrument Calibrations

1. Introduction

1.1 Applicability. A gas dilution system can provide known values of calibration gases through controlled dilution of high-level calibration gases with an appropriate dilution gas. The instrumental test methods in 40 CFR Part 60—e.g., Methods 3A, 6C, 7E, 10, 15, 16, 20, 25A and 25B—require on-site, multi-point calibration using gases of known concentrations. A gas dilution system that produces known low-level calibration gases from high-level calibration gases, with a degree of confidence similar to that for Protocol [1] gases, may be used for compliance tests in lieu of multiple calibration gases when the gas dilution system is demonstrated to meet the requirements of this method. The Administrator may also use a gas dilution system in order to produce a wide range of Cylinder Gas Audit concentrations when conducting performance specifications according to Appendix F, 40 CFR Part 60.

1.2 Principle. The gas dilution system shall be evaluated on one analyzer once during each field test. A precalibrated analyzer is chosen, at the discretion of the source owner or operator, to demonstrate that the gas dilution system produces predictable gas concentrations spanning the range of concentrations expected during the field test. After meeting the requirements of this protocol, the remaining analyzers may be calibrated with the dilution system in accordance to the requirements of the applicable method for the duration of the field test. In Methods 15 and 16, 40 CFR Part 60, Appendix A, reactive compounds may be lost in the gas dilution system. Also, in Methods 25A and 25B, 40 CFR Part 60, Appendix A, calibration with target compounds other than propane is allowed. In these cases, a laboratory evaluation is required once per year in order to assure the Administrator that the system will dilute these reactive gases without significant loss. Note: The laboratory evaluation is required only if the source owner or operator plans to utilize the dilution system to prepare gases mentioned above as being reactive.

2. Specifications

2.1 Gas Dilution System. The gas dilution system shall produce calibration gases whose measured values are within ±2 percent of the predicted values. The predicted values are calculated based on the certified concentration of the supply gas (Protocol gases, when available, are recommended for their accuracy) and the gas flow rates (or dilution ratios) through the gas dilution system.

2.1.1 For gas dilution systems utilizing mass flow controllers, the mass flow controllers in the gas dilution system shall be calibrated against a National Institute of Standards and Technology (NIST) traceable standard according to the manufacturer's instructions once per year.

2.1.2 For gas dilution systems using mass flow controllers, the accuracy of the controllers diminishes at low flow rates. Therefore, it is recommended that flow rates below 10 percent of flow controller capacity be avoided.

2.2 High-Level Supply Gas. An EPA Protocol calibration gas is recommended, due to its accuracy, as the high-level supply gas.

2.3 Mid-Level Supply Gas. An EPA Protocol gas shall be used as an independent check of the dilution system. The concentration of the mid-level supply gas shall be within 10 percent of one of the dilution levels tested in Section 3.2.

3. Performance Tests

3.1 Laboratory Evaluation (Optional). If the gas dilution system is to be used to formulate calibration gases with reactive compounds (Test Methods 15, 16, and 25A/25B (only if using a calibration gas other than propane during the field test) in 40 CFR Part 60, Appendix A), a laboratory certification must be conducted once per year for each reactive compound to be diluted. In the laboratory, carry out the procedures in Section 3.2 on the analyzer required in each respective test method to be laboratory certified (15, 16, or 25A and 25B for compounds other than propane). For each compound in which the gas dilution system meets the requirements in Section 3.2, the source must provide the laboratory certification data for the field test and in the test report.

3.2 Field Evaluation (Required). The gas dilution system shall be evaluated at the test site with an analyzer or monitor chosen by the source owner or operator. It is recommended that the source owner or operator choose a precalibrated instrument with a high level of precision and accuracy for the purposes of this test. This method is not meant to replace the calibration requirements of test methods. In addition to the requirements in this protocol, all the calibration requirements of the applicable test method must also be met.

3.2.1 Prepare the gas dilution system according to the manufacturer's instructions. Using the high-level supply gas, prepare, at a minimum, one dilution for each dilution device utilized in the dilution system. Dilution device in this method refers to the mass flow controller, critical orifice, capillary tube, or any other device which is used to achieve gas dilution. For gas dilution systems utilizing mass flow controllers, it is recommended that two dilutions be performed for each mass flow controller range.

3.2.2 Calculate the predicted concentration for each of the dilutions based on the flow rates through the gas dilution system (or the dilution ratios) and the certified concentration of the high-level supply gas.

3.2.3 Introduce each of the dilutions from Section 3.2.1 into the analyzer or monitor one at a time and determine the instrument response for each of the dilutions.

3.2.4 Repeat the procedure in Section 3.2.3 two times, i.e., until three injections are made at each dilution level. Calculate the average instrument response for each triplicate injection at each dilution level. No single injection shall differ by more than ±2 percent from the average instrument response for that dilution.

3.2.5 For each level of dilution, calculate the difference between the average concentration output recorded by the analyzer and the predicted concentration calculated in Section 3.2.2. The average concentration output from the analyzer shall be within ±2 percent of the predicted value.

3.2.6 Introduce the mid-level supply gas directly into the analyzer, bypassing the gas dilution system. Repeat the procedure twice more, for a total of three mid-level supply gas injections. Calculate the average analyzer output concentration for the mid-level supply gas. The difference between the certified concentration of the mid-level supply gas and the average instrument response shall be within ±2 percent.

3.3 If the gas dilution system meets the criteria listed in Section 3.2, the gas dilution system may be used throughout that field test. If the gas dilution system fails any of the criteria listed in Section 3.2, and the tester corrects the problem with the gas dilution system, the procedure in Section 3.2 must be repeated in its entirety and all the criteria in Section 3.2 must be met in order for the gas dilution system to be utilized in the test.

4. References

4.1 "EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards," EPA–600/R93/224, Revised September 1993.

[FR Doc. 94–18757 Filed 8–2–94; 8:45 am]

BILLING CODE 6560–50–P

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40 CFR Part 180

[PP 7F3521/P587; FRL–4898–7]

RIN 2070–AC18

Pesticide Tolerances for Tefluthrin

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: This document proposes to extend tolerances for the combined