

Title: Revision of the Requirements for Constituent Materials.

Description: The proposed rule would permit the Director of CBER or the Director of CDER, as appropriate, to approve a manufacturer's request for exceptions or alternatives to the regulation for constituent materials. This proposed rule provides manufacturers of biological products with flexibility, as appropriate, to

employ advances in science and technology as they become available, without diminishing public health protections. Manufacturers seeking approval of an exception or alternative must submit a request in writing. The request must be clearly identified with a brief statement describing the basis for the request and supporting data. The request may be submitted as part of the original biologics license application, as

an amendment to the original, pending application or as a prior approval supplement to an approved application. The information to be collected will assist FDA in identifying and reviewing requests for an exception or alternative to the requirements for constituent materials.

Description of Respondents: Manufacturers of biological products.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
610.15	3	1	3	1	3

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

Based on FDA experience, we estimate that we will receive a total of approximately 3 requests annually for an exception or alternative under § 610.15. The hours per response are based on FDA experience with similar information collection requirements.

In compliance with the PRA (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection to OMB (see **DATES** and **ADDRESSES**).

VI. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 610

Biologics, Labeling, Reporting and Recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 610 be amended as follows:

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

1. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371,

372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

2. Amend § 610.15 by adding new paragraph (d) to read as follows:

§ 610.15 Constituent materials.

* * * * *

(d) The Director of the Center for Biologics Evaluation and Research or the Director of the Center for Drug Evaluation and Research may approve an exception or alternative to any requirement in this section. Requests for such exceptions or alternatives must be in writing.

Dated: March 25, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-335P]

RIN 1117-AB28

Schedules of Controlled Substances: Exempted Prescription Product; River Edge Pharmaceutical, Servira

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This Notice of Proposed Rulemaking proposes the amendment of the list of Exempted Prescription Products cited in the Code of Federal Regulations. This action is in response to DEA's review of new applications for exemption. DEA has received one new application for exemption for River

Edge Pharmaceutical's Servira®. Having reviewed this application and relevant information, DEA finds that this preparation has no significant potential for abuse. Therefore, DEA hereby proposes that this product be added to the list of Exempted Prescription Products and exempted from the application of certain provisions of the Controlled Substances Act (CSA).

DATES: Written comments must be postmarked and electronic comments must be submitted on or before April 29, 2010. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after Midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-335" on all written and electronic correspondence. Written comments sent via regular or express mail should be sent to the Drug Enforcement Administration, *Attention:* DEA Federal Register Representative/ODL, 8701 Morrisette Drive, Springfield, VA 22152. Comments may be sent to DEA by sending an electronic message to

dea.diversion.policy@usdoj.gov.

Comments may also be sent electronically through <http://www.regulations.gov> using the electronic comment form provided on that site. An electronic copy of this document is also available at the <http://www.regulations.gov> Web site. DEA will accept attachments to electronic comments in Microsoft word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file formats other than those specifically listed here.

Please note that DEA is requesting that electronic comments be submitted before midnight Eastern time on the day the comment period closes because

<http://www.regulations.gov> terminates the public's ability to submit comments at midnight Eastern time on the day the comment period closes. Commenters in time zones other than Eastern time may want to consider this so that their electronic comments are received. All comments sent via regular or express mail will be considered timely if postmarked on the day the comment period closes.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152, Telephone (202) 307-7183.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted on <http://www.regulations.gov>.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in the Drug Enforcement Administration's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the

agency's public docket file in person by appointment, *please see* the **FOR FURTHER INFORMATION CONTACT** paragraph.

Background

The Controlled Substances Act as amended by the Dangerous Drug Diversion Control Act of 1984 authorizes the Attorney General in accordance with 21 U.S.C. 811(g)(3)(A) to exempt from specific provisions of the Act, a preparation or mixture if that preparation or mixture: (1) Contains a nonnarcotic controlled substance; (2) is approved for prescription use; and (3) contains one or more active ingredients that are not listed in any schedule and whose presence vitiates the potential for abuse of the nonnarcotic controlled substance. Such exemptions apply only to a specific prescription product and are only granted following suitable application to the Drug Enforcement Administration per 21 CFR 1308.31.

Exemption of Nonnarcotic Prescription Products

21 CFR 1308.31 provides an application procedure whereby any person may apply for exemption for nonnarcotic prescription products which meet certain criteria. 21 CFR 1308.31(a) further states that any person seeking to have any compound, mixture, or preparation containing any nonnarcotic controlled substance listed in 21 CFR 1308.12(e), or in 21 CFR 1308.13(b) or (c), or in 21 CFR 1308.14, or in 21 CFR 1308.15, exempted from application of all or any part of the CSA pursuant to 21 U.S.C. 811(g)(3)(A) may apply to the Administrator of DEA for such exemption.

21 CFR 1308.31(b) specifies that an application for an exemption shall contain the following information:

- (1) The complete quantitative composition of the dosage form.
- (2) Description of the unit dosage form together with complete labeling.
- (3) A summary of the pharmacology of the product including animal investigations and clinical evaluations and studies, with emphasis on the psychic and/or physiological dependence liability (this must be done for each of the active ingredients separately and for the combination product).
- (4) Details of synergisms and antagonisms among ingredients.
- (5) Deterrent effects of the noncontrolled ingredients.
- (6) Complete copies of all literature in support of claims.
- (7) Reported instances of abuse.
- (8) Reported and anticipated adverse effects.

(9) Number of dosage units produced for the past 2 years.

Within a reasonable period of time after the receipt of an application for an exemption under this section, 21 CFR 1308.31(c) states that the Administrator shall notify the applicant of the acceptance or non-acceptance of the application, and if not accepted, the reason therefor. The regulation states that the Administrator need not accept an application for filing if any of the requirements prescribed in 21 CFR 1308.31(b) is lacking or is not set forth so as to be readily understood. The regulation states that if accepted for filing, the Administrator shall publish in the **Federal Register** a general notice of proposed rulemaking in granting or denying the application. Such notice shall include a reference to the legal authority under which the rule is proposed, a statement of the proposed rule granting or denying an exemption, and, in the discretion of the Administrator, a summary of the subjects and issues involved.

The regulation further specifies that the Administrator shall permit any interested person to file written comments on or objections to the proposal and shall designate in the notice of proposed rulemaking the time during which such filings may be made. After consideration of the application and any comments on or objections to the proposed rulemaking, the Administrator shall issue and publish in the **Federal Register** a final order on the application, which shall set forth the findings of fact and conclusions of law upon which the order is based. This order shall specify the date on which it shall take effect, which shall not be less than 30 days from the date of publication in the **Federal Register** unless the Administrator finds that conditions of public health or safety necessitate an earlier effective date, in which event the Administrator shall specify in the order his findings as to such conditions.

21 CFR 1308.31(d) further states that the Administrator may revoke any exemption granted pursuant to 21 U.S.C. 811(g)(3)(A) by following the procedures set forth in 21 CFR 1308.31(c).

Redelegation of Authority

The Administrator has redelegated this authority to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, pursuant to 28 CFR 0.104, Appendix to Subpart R. The current Table of Exempted Prescription Products lists those products that have been granted exempt status prior to this

update. That table can be viewed online at: http://www.deadiversion.usdoj.gov/schedules/exempt/exempt_list.htm.

Product Exemptions Subject to This Proposed Rulemaking

DEA received one application for exemption pursuant to the provisions of 21 CFR 1308.32 for:

River Edge Pharmaceutical's Servira® (NDC Code 68032-256) tablets containing 48.6 mg phenobarbital in combination with hyoscyamine sulfate, atropine sulfate and scopolamine hydrobromide.

The Deputy Assistant Administrator, Office of Diversion Control, having reviewed this application and relevant information, finds that this preparation contains a nonnarcotic controlled substance listed in 21 CFR 1308.14, also contains an active ingredient not listed in any controlled substance schedule, and has no significant potential for abuse.

The product Servira® contains the drug phenobarbital. Phenobarbital is a schedule IV controlled substance listed in 21 CFR 1308.14. The product also contains the anticholinergic ingredients hyoscyamine sulfate, atropine sulfate and scopolamine hydrobromide. These ingredients are not controlled substances. In the quantities included in the product, these ingredients have deterrent effects upon the product's potential for abuse.

Therefore, the Deputy Assistant Administrator hereby proposes that the following product is to be exempted from the application of sections 302 through 305, 307 through 309, and 1002 through 1004 of the Act (21 U.S.C. 822-825, 827-829, and 952-954) and §§ 1301.13, 1301.22, and 1301.71 through 1301.77 of this chapter. If this rule is finalized as proposed, the table that is available online will be updated to include the exempted prescription product included in this rulemaking.

Any interested person may file written comments or objections to this

proposal. After consideration of the application and any comments or objections to the proposed rulemaking, the Deputy Assistant Administrator shall issue and publish in the **Federal Register** the final order of the application. The Deputy Assistant Administrator may revoke any exemption granted pursuant to 21 U.S.C. 811(g)(3)(A) by following the procedures set forth in 21 CFR 1308.31(c).

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601-612), and by approving it certifies that this regulation will not have a significant economic impact upon a substantial number of small entities. This regulation will not have a significant impact upon firms who distribute these products. In fact, the approval of Exempted Prescription status for these products reduces the regulatory requirements for distribution of these materials.

Executive Order 12866

The Deputy Assistant Administrator further certifies that this rulemaking has been drafted in accordance with the principles of Executive Order 12866 Section 1(b). It has been determined that this is not a significant regulatory action. Therefore, this action has not been reviewed by the Office of Management and Budget.

Executive Order 12988

The Deputy Assistant Administrator further certifies that this regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988.

Executive Order 13132

This rulemaking does not preempt or modify any provision of State law; nor

does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Under the authority vested in the Attorney General by section 202(d) of the Act (21 U.S.C. 811(g)(3)(B)) and delegated to the Administrator of the Drug Enforcement Administration by regulations of the Department of Justice (28 CFR Part 0.100), and redelegated to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, the Deputy Assistant Administrator hereby proposes to amend the Table of Exempted Prescription Products cited in § 1308.32 by adding the following:

Company	Trade name	NDC code	Form	Controlled substance	(mg or mg/ml)
River's Edge Pharmaceutical	Servira	68032-256	TB	Phenobarbital	48.6

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

Dated: March 12, 2010.

Joseph T. Rannazzisi,
Deputy Assistant Administrator, Office of
Diversion Control.

[FR Doc. 2010-6035 Filed 3-29-10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R06-OAR-2010-0147; FRL-9130-4]

Approval and Promulgation of Air Quality Implementation Plans; Texas; Revisions to the Emission Credit Banking and Trading Program

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve severable portions of two revisions to the Texas State Implementation Plan (SIP) submitted by the State of Texas on October 24, 2006, and August 16, 2007. These revisions amend existing sections and create a new section in Title 30 of the Texas Administrative Code (TAC), Chapter 101—General Air Quality Rules, Subchapter H—Emissions Banking and Trading, Division 1—Emission Credit Banking and Trading, referred to elsewhere in this notice as the Emission Reduction Credit (ERC) Program. The October 24, 2006, submittal creates a new section for international emission reduction provisions and amends existing sections to further clarify procedures for using emission protocols and to update the approved list of emission credit uses. The August 16, 2007, submittal amends two sections of the ERC program to update cross-references to recently recodified 30 TAC Chapter 117 provisions. EPA has determined that these SIP revisions comply with the Clean Air Act and EPA regulations, are consistent with EPA policies, and will improve air quality. This action is being taken under section 110 and parts C and D of the Federal Clean Air Act (the Act or CAA).

DATES: Comments must be received on or before *April 29, 2010*.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R06-OAR-2010-0147, by one of the following methods:

(1) <http://www.regulations.gov>: Follow the on-line instructions for submitting comments.

(2) *E-mail:* Mr. Jeff Robinson at robinson.jeffrey@epa.gov. Please also cc the person listed in the **FOR FURTHER INFORMATION CONTACT** paragraph below.

(3) *U.S. EPA Region 6 "Contact Us" Web site:* <http://epa.gov/region6/r6coment.htm>. Please click on "6PD" (Multimedia) and select "Air" before submitting comments.

(4) *Fax:* Mr. Jeff Robinson, Chief, Air Permits Section (6PD-R), at fax number 214-665-6762.

(5) *Mail:* Mr. Jeff Robinson, Chief, Air Permits Section (6PD-R), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202-2733.

(6) *Hand or Courier Delivery:* Mr. Jeff Robinson, Chief, Air Permits Section (6PD-R), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202-2733. Such deliveries are accepted only between the hours of 8:30 a.m. and 4:30 p.m. weekdays except for legal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-R06-OAR-2010-0147. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. Do not submit information through <http://www.regulations.gov> or e-mail, if you believe that it is CBI or otherwise protected from disclosure. The <http://www.regulations.gov> Web site is an "anonymous access" system, which means that EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment along with any disk or CD-ROM submitted. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters and any form of encryption and should be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA

Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

Docket: All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at the Air Permits Section (6PD-R), Environmental Protection Agency, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202-2733. The file will be made available by appointment for public inspection in the Region 6 FOIA Review Room between the hours of 8:30 a.m. and 4:30 p.m. weekdays except for legal holidays. Contact the person listed in the **FOR FURTHER INFORMATION CONTACT** paragraph below to make an appointment. If possible, please make the appointment at least two working days in advance of your visit. A 15 cent per page fee will be charged for making photocopies of documents. On the day of the visit, please check in at the EPA Region 6 reception area on the seventh floor at 1445 Ross Avenue, Suite 700, Dallas, Texas.

The State submittal related to this SIP revision, and which is part of the EPA docket, is also available for public inspection at the State Air Agency listed below during official business hours by appointment:

Texas Commission on Environmental Quality, Office of Air Quality, 12124 Park 35 Circle, Austin, Texas 78753.

FOR FURTHER INFORMATION CONTACT: If you have questions concerning today's proposed rule, please contact Ms. Adina Wiley (6PD-R), Air Permits Section, Environmental Protection Agency, Region 6, 1445 Ross Avenue (6PD-R), Suite 1200, Dallas, TX 75202-2733. The telephone number is (214) 665-2115. Ms. Wiley can also be reached via electronic mail at wiley.adina@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document wherever, any reference to "we," "us," or "our" is used, we mean EPA.

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