

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DELAWARE RIVER BASIN COMMISSION

### 18 CFR Part 401

#### Rules of Practice and Procedure; Proposed Amendments to Administrative Manual—Rules of Practice and Procedure; Public Hearing

**AGENCY:** Delaware River Basin Commission.

**ACTION:** Notice of proposed rulemaking and public hearing.

**SUMMARY:** Notice is hereby given that the Delaware River Basin Commission will hold a public hearing to review comments on proposed amendments to its Rules of Practice and Procedure which are intended to delete obsolete provisions, to clarify certain provisions of the rules and better inform the signatory parties, applicants and the general public with regard to the Commission's practices and procedures. The proposed revisions conform the rules to existing Commission interpretations and practices.

**DATES:** The public hearing will be held on October 22, 1997 beginning at 3:00 p.m. and continuing until 5:00 p.m., as long as there are people present wishing to testify.

The deadline for inclusion of written comments in the hearing record will be announced at the hearing.

**ADDRESSES:** The public hearing will be held in the Goddard Conference Room of the Commission's offices at 25 State Police Drive, West Trenton, New Jersey. Written comments should be submitted to Susan M. Weisman, Delaware River Basin Commission, P.O. Box 7360, West Trenton, New Jersey 08628.

#### FOR FURTHER INFORMATION CONTACT:

Susan M. Weisman, Commission Secretary, Delaware River Basin Commission, P.O. Box 7360, West Trenton, New Jersey 08628. Telephone (609) 883-9500 ext. 203.

#### SUPPLEMENTARY INFORMATION:

##### Background and Rationale

The Rules of Practice and Procedure of the Delaware River Basin Commission have been modified and changed periodically since they were originally adopted December 13, 1961. There has not been a comprehensive review of these rules, however, for more than twenty years.

The proposed revisions are summarized below.

##### 1. Deletion of Article 4, Environmental Impact Statements, and Related Sections

Existing Article 4 sets forth DRBC's requirements with regard to environmental impact statements and reviews. Although these provisions have remained in DRBC's Rules, a copy of DRBC Resolution No. 80-11 suspending those provisions of the Commission's Rules of Practice and Procedure relating to environmental assessments has been inserted at the end of the existing rules. Since the adoption of this Resolution in 1980, the Commission has not conducted environmental assessments pursuant to DRBC's rules. The continued inclusion of these suspended sections, however, has been a source of confusion and misunderstanding to many individuals and groups interested in DRBC's review requirements. For example, when DRBC recently solicited public comments concerning its regulations for controlling toxic pollutants in the Delaware River Estuary, comments were received suggesting that DRBC had not complied with the environmental review requirements under its rules.

When Resolution No. 80-11 to suspend was adopted, the Resolution would have permitted reinstatement of environmental reviews if "financial resources are developed." The experiences of the last 17 years, and the financial constraints that have developed recently, make it clear that Federal or other funding is not likely to be available for the foreseeable future.

To avoid continuing confusion, the deletion of Article 4 is proposed. DRBC's review of projects, however, will continue to require all projects to comply with all environmental and other policies in the Commission's Comprehensive Plan.

##### 2. Review of Projects Having a Non-Substantial Impact on Basin Waters

In 1976 the Commission adopted Resolution No. 76-20 which provided two administrative changes designed to reduce the project review activity of DRBC staff.

The first was an attempt to provide more flexibility in the determination of what constitutes substantial projects resulting in more projects determined to be nonsubstantial and not subject to Commission review. Experience with a few projects indicated the process was not cost effective and staff reverted back to strictly following the exemptions list in the Rules Section 2.3.5(a). The 1976 revisions included in Sections 2.3.4 and 2.3.5(d) which provided for this procedure have not been applied since 1978.

The second administrative change provided for in Sections 2.3.5(e), 2.3.9 (b) and (c) was to have state staff review and submit a determination (called an action report) that each project forwarded to the Commission did not impair or conflict with the DRBC's Comprehensive Plan. Even though three states signed new administrative agreements to implement this procedure, state staffs did not provide the determinations and the procedure was never implemented.

Section 2.3.10 is proposed to be deleted and all rules regarding hearings are proposed to be consolidated in revised Article 6.

#### Summary of Proposed Revisions

##### 1. Introduction

In view of the changes included within the proposed revision, the Introduction has been rewritten to update the description of what is included in the Commission's Rules of Practice and Procedure.

##### 2. Article 1—Comprehensive Plan

The proposed revisions to this article clarify the meaning of Comprehensive Plan within DRBC's rules. The revisions further clarify the procedure related to application for inclusion of projects within the Comprehensive Plan and the review by the Commission of proposals for changes and additions to the Comprehensive Plan. These revisions conform with existing Commission interpretation of the provisions within Article 1.

### 3. Article 2—Water Resources Program

No proposed revisions to this article are recommended at this time.

### 4. Article 3—Project Review Under Section 3.8 of the Compact

(a) The proposed revisions to Article 3 relating to environmental reviews and non-substantial projects are discussed above.

(b) The proposed revision would delete Section 2–3.5.1. The regionalization policy was slightly modified with the adoption of revised Water Quality Regulations in December 1992 (Section 2.30, Basin Regulation—Water Quality). Deleting these requirements eliminates confusion and allows the more recent and flexible policy to control. The revised rule would add (6) in Section 2.1.4 requiring applications to include a discussion of the alternates considered and in Section 2.3.8 (a) “Exhibits to Accompany Application”, it would revise (8) to include analysis and conclusions of regional water supply and waste water investigations.

(c) The proposed revision would also delete Section 2.3.5.2. This policy was adopted in 1971, Resolution No. 71–3, when the DRBC was involved in four or five nuclear plants and several major expansions or new fossil fuel plants, all by the seven major electric utilities serving the Basin. Planning at that time centered around mega stations of 1000 to 3000 Megawatts and use of multi MGD of water. Future locations of such large single use water demands was essential for any future water resource planning. A consortium of the utilities was formed known as DRBEUG (Delaware River Basin Electric Utilities Group) to address this DRBC requirement. Between 1971 and 1989, periodic siting studies were submitted to DRBC. In 1989 DRBEUG explained that they no longer could present a comprehensive siting study since the regulators were now encouraging NUGs (Non Utility Generators) and they could not in any way appear to represent these non-utility electric generators. Essentially, the major utilities have abandoned plans for any new major stations. New applications for several years now have been non-utility projects and generally no more than 200 MW. After several meetings between DRBEUG and staff, it was concluded that the siting study would no longer serve its intended purpose for DRBC.

(d) The remaining sections are intended to clarify the Commission's procedures with regard to Section 3.8 applications and the review thereof.

### 5. Article 4—Environmental Impact Statements

The Commission proposes deletion of the existing provisions of Article 4 as discussed above. Article 4 will be reserved for future use.

### 6. Article 5—Review in Water Quality Cases

The proposed revisions to Article 5 clarify that this article applies to administrative actions and decisions by the Executive Director. The procedures for review, hearing and decisions of objections to the Executive Director's actions and decisions will be pursuant to Article 6. The time for requesting a hearing is extended to thirty days to conform with the thirty day period provided for in Article 6. The remaining proposed changes are to broaden the wasteload allocations section to cover allocations in general (including proposed allocations of toxics) as well as the existing allocation program of carbonaceous oxygen demand.

### 7. Article 6—Conduct of Hearings

The proposed revisions in this article reflect the practices employed by the Commission in connection with hearings, clarify the application of Article 6 to contested hearings and codify existing practices with regard to such hearings.

### 8. Articles 7, 8 and 9

No changes to these articles are proposed at this time.

Copies of the full text of the proposed amendments to the Administrative Manual—Rules of Practice and Procedure may be obtained by contacting Susan M. Weisman at the address provided in **FOR FURTHER INFORMATION CONTACT**. Persons wishing to testify are requested to notify the Secretary in advance.

Dated: August 18, 1997.

Delaware River Basin Compact, 75 Stat. 688.

**Susan M. Weisman,**

*Secretary.*

[FR Doc. 97–23058 Filed 8–28–97; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 336, 338, 341, and 348

[Docket No. 97N–0128]

RIN 0910–AA01

#### Labeling of Diphenhydramine-Containing Drug Products for Over-the-Counter Human Use

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend the tentative final monograph for over-the-counter (OTC) external analgesic drug products, and the final monographs for oral OTC diphenhydramine drug products for antiemetic, antihistamine, antitussive, and nighttime sleep-aid indications. The amendment adds warning statements concerning diphenhydramine toxicity. The proposed warnings advise consumers not to use topical products containing diphenhydramine on chicken pox, poison ivy, sunburn, large areas of the body, blistered or oozing skin, more often than directed, or with any other product containing diphenhydramine, even one taken by mouth, and not to use oral OTC diphenhydramine products with any other product containing diphenhydramine including products used topically. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

**DATES:** Submit written comments by November 28, 1997. FDA is proposing that any final rule that may issue based on this proposal become effective 12 months 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Nahid Mokhtari-Rejali, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Diphenhydramine hydrochloride is proposed for inclusion in the monograph for OTC external analgesic drug products for topical use as an antihistamine external analgesic.