

the concerns associated with phenolphthalein. Finally, the agency considers the phenolphthalein portion of this proposed rule to be a pressing public health concern because the ingredient is still being used in some drug products and genetic damage and risk of malignancy could occur at doses that are likely to be used by humans.

FDA therefore finds that there is good cause for a 30-day comment period and an immediate effective date.

#### VIII. Paperwork Reduction Act of 1995

FDA tentatively concludes that labeling requirements related to this proposed rule are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, this proposed rulemaking involves labeling that is a "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

#### IX. Environmental Impact

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.

#### X. Request for Comments

Interested persons may, on or before October 2, 1997 submit written comments on this proposed rule to the Dockets Management Branch (address above). Written comments on the agency's economic impact determination may be submitted on or before October 2, 1997. Three copies of all comments or objections are to be submitted, except that individuals may submit one copy. Comments should 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 and objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

#### List of Subjects

##### 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

##### 21 CFR Part 334

Labeling, 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 parts 310 and 334 (as proposed in the **Federal Register** of January 15, 1985 (50 FR 2124)) be amended as follows:

#### PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

**Authority:** Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512–516, 520, 601(a), 701, 704, 705, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b–360f, 360j, 361(a), 371, 374, 375, 379e); secs. 215, 301, 302(a), 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b–263n).

2. Section 310.545 is amended by redesignating the text of paragraph (a)(12)(iv) as (a)(12)(iv)(A), by adding new (a)(12)(iv)(B) heading and paragraphs (a)(12)(iv)(B) and (d)(29), and by revising paragraph (d) introductory text and paragraph (d)(1) to read as follows:

##### § 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) \* \* \*  
(12) \* \* \*

(iv)(A) *Stimulant laxatives*—  
*Approved as of May 7, 1991.* \* \* \*

(B) *Stimulant laxatives*—*Approved as of* (date of publication in the **Federal Register**).

Danthron

Phenolphthalein

\* \* \* \* \*

(d) Any OTC drug product that is not in compliance with this section is subject to regulatory action if initially introduced or initially delivered for introduction into interstate commerce after the dates specified in paragraphs (d)(1) through (d)(29) of this section.

(1) May 7, 1991, for products subject to paragraphs (a)(1) through (a)(2)(i), (a)(3) through (a)(4), (a)(6)(i)(A), (a)(6)(ii)(A), (a)(7) (except as covered by paragraph (d)(3) of this section), (a)(8)(i), (a)(10)(i) through (a)(10)(iii), (a)(12)(i) through (a)(12)(iv)(A), (a)(14) through (a)(15)(i), and (a)(16) through (a)(18) of this section.

\* \* \* \* \*

(29) September 2, 1997 for products subject to paragraph (a)(12)(iv)(B) of this section.

#### PART 334—LAXATIVE DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

3. The authority citation for 21 CFR part 334 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).

##### § 334.18 [Amended]

4. Section 334.18 *Stimulant laxative active ingredients* is amended by removing paragraphs (e) and (g) and redesignating paragraphs (f) and (h) as paragraphs (e) and (f), respectively.

##### § 334.30 [Amended]

5. Section 334.30 *Permitted combinations of active laxative ingredients* is amended by removing paragraph (e)(4) and removing and reserving paragraph (h)(2).

##### § 334.32 [Amended]

6. Section 334.32 *Bowel cleansing systems* is amended by removing and reserving paragraph (b).

##### § 334.60 [Amended]

7. Section 334.60 *Labeling of stimulant laxative drug products* is amended by removing paragraph (c)(2) and redesignating paragraph (c)(3) as paragraph (c)(2) and by removing paragraphs (d)(9) and (d)(11) and redesignating paragraphs (d)(10), (d)(12), and (d)(13) as paragraphs (d)(9), (d)(10), and (d)(11), respectively.

##### § 334.66 [Amended]

8. Section 334.66 *Labeling of bowel cleansing systems identified in § 334.32* is amended by removing the words "and (b)" in paragraph (a) and by removing and reserving paragraphs (c)(2) and (d)(3)(iii)(B).

Dated: August 20, 1997.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 97–23122 Filed 8–29–97; 8:45 am]

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#### NATIONAL INDIAN GAMING COMMISSION

##### 25 CFR Part 502

##### Indian Gaming Regulatory Act of 1988; Definitions

**AGENCY:** National Indian Gaming Commission.

**ACTION:** Advance notice of proposed rulemaking.

**SUMMARY:** This notice announces the initiation of the rulemaking process and requests information relevant to amending the National Indian Gaming Commission's (NIGC) definition regulations located at 25 CFR 502.7 and 502.8. These regulations define key terms in the Indian Gaming Regulatory Act of 1988. The regulations are intended to provide guidance to tribes, their attorneys, enforcement personnel and others interested in Indian gaming. The Commission is inviting the public to comment and assist the NIGC in determining the need, if any, for additional rules governing this area.

**DATES:** Comments in response to this advance notice must be submitted by November 3, 1997.

**ADDRESSES:** Commenters may submit their comments by mail, facsimile, or delivery to: Definition Rule Comments, National Indian Gaming Commission, Suite 9100, 1441 L Street NW., Washington, DC 20005. Fax number: 202-632-7066 (not a toll-free number). Public comments may be delivered or inspected from 9 a.m. until noon and from 2 p.m. to 5 p.m. Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Darla M. Silva at 202-632-7003, or by facsimile at 202-632-7066 (not toll-free numbers).

#### SUPPLEMENTARY INFORMATION:

##### 1. Introduction

The Indian Gaming Regulatory Act (IGRA, or the Act), 25 U.S.C. § 2701 et seq., was signed into law on October 17, 1988. The Act established the National Indian Gaming Commission (the Commission). IGRA was enacted to establish a comprehensive system for regulating gambling activities on Indian lands. IGRA divides gaming into three categories or classes. Class I gaming consists of social gaming for minimal prizes and traditional gaming and is regulated exclusively by the tribes. 25 U.S.C. 2703(6), 2710(a)(1). Class II gaming consists of bingo, pull-tabs, bingo-like games, and non-banking card games. 25 U.S.C. 2703(7)(A). A tribe may conduct, license, and regulate class II gaming if: (1) The state in which the tribe is located permits such gaming for any purpose by any person, organization, or entity; and (2) the governing body of the tribe adopts a gaming ordinance which is approved by the Chairman of the National Indian Gaming Commission. 25 U.S.C. 2710(a)(2) and (b).

All forms of gaming not included in either class I or class II, such as banking card games (e.g., blackjack), casino games, slot machines, and electronic

facsimiles of any game of chance are designated as class III gaming under the IGRA. 25 U.S.C. 2703(8). Class III gaming may lawfully be conducted by an Indian tribe if: (1) The state in which the tribe is located permits such gaming for any purpose by any person, organization, or entity; (2) the tribe and the state have negotiated a tribal-state compact which has been approved by the Secretary of the Interior; and (3) the tribe has adopted a gaming ordinance which has been approved by the Chairman of the Commission. 25 U.S.C. 2710(d)(1).

The IGRA expressly authorizes the Commission to "promulgate such regulations and guidelines as it deems appropriate to implement the provisions of this [Act]." 25 U.S.C. 2706(b)(10). On April 9, 1992, the Commission published final rules (57 FR 12392) defining key statutory terms, including "electronic, computer or other technologic aid" and "electronic or electromechanical facsimile". The current definitions are as follows:

*Electronic, computer or other technologic aid* means a device such as a computer, telephone, cable, television, satellite or bingo blower and that when used—

- (a) Is not a game of chance but merely assist a player or the playing of a game;
- (b) Is readily distinguishable from the playing of a game of chance on an electronic or electromechanical facsimile; and
- (c) Is operated according to applicable Federal communications law. 25 CFR 502.7.

*Electronic or Electromechanical facsimile* means any gambling device as defined in 15 U.S.C. § 1171(a) (2) or (3). 25 CFR 502.8.

Since the adoption of these regulations, there has been controversy regarding what constitutes an "aid" and a "facsimile" and the difference between them. The Commission is requesting public comments to assist in its evaluation of whether amendment of its current regulations is necessary.

##### 2. Advance Notice of Proposed Rulemaking

After consideration of this issue, the NIGC has determined that the appropriate course of action is to publish an Advance Notice of Proposed Rulemaking to collect further information. Concurrently with the collection of this information, the Agency will enforce existing regulations.

The issue of how best to amend the current regulations, if at all, is a question with implications for tribal governments, state governments and other Federal officials. Before the Commission proceeds in this area, it intends to have the benefit of a full airing of the issues through the public comment process.

##### 3. Request for Comments

Public comment is requested to assist the NIGC in its evaluation of the decision to amend its current definition regulations. Comment is requested on the following issues:

- (1) The effectiveness of the current regulations is distinguishing between a class II aid and a class III facsimile;
- (2) Any suggestions for alternative definitions and/or interpretations.

##### 4. Public Participation

Interested parties are invited to submit comments on any or all of these and other pertinent issues related to amending the current definition regulations by November 3, 1997, in quadruplicate to the Definition Rule Comments, National Indian Gaming Commission, Suite 9100, 1441 L Street NW., Washington, DC 20005. Fax number: 202-632-7066 (not a toll-free number). All written comments submitted in response to this notice will be available for inspection and copying in the NIGC office from 9 a.m. until noon and from 2 p.m. to 5 p.m. Monday through Friday. All timely written submissions will be considered in determining the nature of any proposal.

##### Authority and Signature

This advance notice of proposed rulemaking was prepared under the direction of Tom Foley, Vice Chairman, National Indian Gaming Commission, 1441 L St., NW., Suite 9100, Washington, DC 20005.

Signed at Washington, DC this 21st day of August, 1997.

**Tom Foley,**

*Vice Chairman, National Indian Gaming Commission.*

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#### ENVIRONMENTAL PROTECTION AGENCY

##### 40 CFR Part 52

[MD040-3018b; FRL-5881-7]

##### Approval and Promulgation of Air Quality Implementation Plans; Maryland; Control of Volatile Organic Compound Emissions From Sheet-Fed and Web Lithographic Printing and Paper Coatings

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the State of