intersection of the Humble VORTAC 20-mile DME arc and the Humble VORTAC 293° radial; thence clockwise on the Humble VORTAC 20-mile DME arc to the intersection of the Humble VORTAC 20-mile DME arc and the Humble VORTAC 058° radial; thence east to the intersection of the Humble VORTAC 30-mile DME arc and the Humble VORTAC 067° radial; thence clockwise on the Humble VORTAC 30-mile DME arc to the intersection of the Humble VORTAC 30-mile DME arc and the Humble VORTAC 096° radial; thence west to the intersection of the Humble VORTAC 20-mile DME arc and the Humble VORTAC 101° radial; thence counterclockwise on the Humble VORTAC 20-mile DME arc to the intersection of the Humble VORTAC 20-mile DME arc and the Humble VORTAC 058° radial; thence west to the intersection of the Humble VORTAC 15-mile DME arc and the Humble VORTAC 048° radial; thence counterclockwise on the Humble VORTAC 15-mile DME arc to the intersection of the Humble VORTAC 15-mile DME arc and the Humble VORTAC 303° radial; thence west to the intersection of the Humble VORTAC 20-mile DME arc and the Humble VORTAC 293° radial; thence counterclockwise on the Humble VORTAC 20-mile DME arc to the intersection of the Humble VORTAC 20-mile DME arc and the Humble VORTAC 249° radial; thence east to the intersection of the Humble VORTAC 15-mile DME arc and the Humble VORTAC 242° radial; thence counterclockwise along the Humble VORTAC 15-mile DME arc to lat. 29°43′40″ N., long. 95°27′40″ W.; thence southwest along SH 59 to the point of beginning; and that airspace beginning at the intersection of the 15-mile arc and the 211° bearing from the point of origin; thence clockwise along the 15-mile arc to the intersection of the 15-mile arc and the 254° bearing from the point of origin; thence southwest to the intersection of the 20-mile arc and the 248° bearing from the point of origin; thence counterclockwise along the 20-mile arc from the point of origin to the intersection of the 20-mile arc and the 211° bearing from the point of origin; thence northeast along the 211° bearing from the point of origin to the intersection of the 10-mile arc and the 211° bearing from the point of origin; thence counterclockwise along the 10-mile arc to the intersection of the 10-mile arc and the 156° bearing from the point of origin; thence southeast along the 156° bearing to the 15-mile arc and 156° bearing from the point of origin; thence clockwise along the 15-mile arc from the point of origin to the point of beginning.

Area D. That airspace extending upward from 4,000 feet MSL to and including 10,000 feet MSL bounded by a line beginning at the intersection of SH 59 and the Humble VORTAC 30-mile DME arc; thence clockwise along the Humble VORTAC 30-mile DME arc to the intersection of the Humble VORTAC 30-mile DME arc and the Humble VORTAC 254° radial; thence east to the intersection of the Humble VORTAC 20-mile DME arc and the Humble VORTAC 249° radial; thence counterclockwise on the Humble VORTAC 20-mile DME arc to the intersection of the Humble VORTAC 20-mile DME arc and SH 59; thence southwest to and along SH 59 to the intersection of the 15-mile arc from the point of origin and SH 59; thence counterclockwise on the 15-mile arc from the point of origin to the intersection of the 15-mile arc from the point of origin and the 254° bearing from the point of origin; thence southwest to the intersection of the 20-mile arc from the point of origin and the 248° bearing from the point of origin; thence clockwise on the 20-mile arc from the point of origin to the intersection of the 20-mile arc from the point of origin and SH 59; thence southwest along SH 59 to the point of beginning; and that airspace beginning at the intersection of the 211° bearing and the 20-mile arc from the point of origin; thence northeast to the intersection of the 15-mile arc from the point of origin and the 211° bearing from the point of origin; thence counterclockwise on the 15-mile arc from the point of origin to the intersection of the 15-mile arc from the point of origin and I–10; thence east along I–10 to the intersection of the Humble VORTAC 20-mile DME arc and I–10; thence counterclockwise on the Humble VORTAC 20-mile DME arc to the intersection of the Humble VORTAC 20-mile DME arc and the Humble VORTAC 101° radial; thence east to the intersection of the Humble VORTAC 30-mile DME arc and the Humble VORTAC 096° radial; thence clockwise on the Humble VORTAC 30-mile DME arc until the intersection of the Humble VORTAC 30-mile DME arc and the 20-mile arc from the point of origin; thence clockwise on the 20-mile arc from the point of origin to the intersection of the 20-mile arc from the point of origin and the 248° bearing from the point of origin; thence southwest to the intersection of the 25-mile arc from the point of origin and the 245° bearing from the point of origin; thence counterclockwise on the 25-mile arc from the point of origin to the intersection of the 25-mile arc from the point of origin and the 211° bearing from the point of origin; thence northeast on the 211° bearing from the point of origin to the point of beginning; and that airspace beginning at the intersection of the Humble VORTAC 20-mile DME arc and the Humble VORTAC 293° radial; thence west to the intersection of the Humble VORTAC 30-mile DME arc and the Humble VORTAC 283° radial; thence clockwise along the Humble VORTAC 30-mile DME arc to the intersection of the Humble VORTAC 30-mile DME arc and the Humble VORTAC 067° radial; thence west to the intersection of the Humble VORTAC 20-mile DME arc and the Humble VORTAC 058° radial; thence counterclockwise along the Humble VORTAC 20-mile DME arc to the point of beginning.

Area E. That airspace extending upward from 2,500 feet MSL to and including 10,000 feet MSL bounded by a line beginning at the intersection of the 15-mile arc from the point of origin and SR 6; thence southeast along SR 6 to the intersection of SR 6 and FR 521; thence south along FR 521 to the intersection of FR 521 and the 15-mile arc from the point of origin; thence clockwise along the 15-mile arc from the point of origin to the point of the beginning.

* * * * *

Issued in Washington, DC, on April 10, 2003.

Reginald C. Matthews,

Manager, Airspace and Rules Division.

[FR Doc. 03–9504 Filed 4–16–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 335

[Docket No. 78N–036T]

RIN 0910–AA01

Antidiarrheal Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a proposed rule that would amend the final monograph for over-the-counter (OTC) antidiarrheal drug products to include relief of travelers' diarrhea as an indication for products containing bismuth subsalicylate. Travelers' diarrhea occurs in travelers and is most commonly caused by an infectious agent. This proposal is part of FDA's ongoing review of OTC drug products.

DATES: Submit written or electronic comments by July 16, 2003; written or electronic comments on the agency's economic impact determination by July 16, 2003. Please see section VIII of this document for the effective date of any final rule that may publish based on this proposal.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Mary S. Robinson, 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

In the **Federal Register** of March 21, 1975 (40 FR 12902), FDA published under 21 CFR 330.10(a)(6) an advance notice of proposed rulemaking to establish a monograph for OTC antidiarrheal drug products, together with the recommendations of the

Advisory Review Panel on OTC Laxative, Antidiarrheal, Emetic, and Antiemetic Drug Products, which evaluated these drug classes. The proposed rule was published in the **Federal Register** of April 30, 1986 (51 FR 16138), as a tentative final monograph.

In response to the proposed rule, one manufacturer requested a travelers' diarrhea claim for bismuth subsalicylate (Ref. 1). Travelers' diarrhea is an acute diarrheal illness occurring among travelers, particularly those visiting developing countries where sanitation is suboptimal. Virtually all cases of travelers' diarrhea are caused by infectious agents, acquired through the ingestion of fecally contaminated food and/or water. Bacterial pathogens account for the great majority of episodes. Overall, one of the most common etiologic agents in travelers' diarrhea are enterotoxigenic *Escherichia coli*, which are responsible for 50 to 75 percent of episodes in certain areas of the world. Other recognized enteropathogens can be isolated from most of the remainder of cases, but with great regional differences in prevalence. Viruses (rotavirus, Norwalk-like virus) and protozoa (amebas, Giardia) are collectively responsible for fewer than 10 percent of cases of travelers' diarrhea (Ref. 2).

The clinical data for this claim are discussed in section II, comment 3 of the final rule for OTC antidiarrheal drug products, published elsewhere in this issue of the **Federal Register**. The agency has tentatively determined that the data support the use of bismuth subsalicylate in treating the symptoms of travelers' diarrhea. Accordingly, the agency is proposing to amend the final monograph to include ''relieves travelers' diarrhea'' as a monograph indication for OTC antidiarrheal drug products containing bismuth subsalicylate identified in § 335.10(a).

II. Summary of the Agency's Proposal for Travelers' Diarrhea

The agency proposes to add the following definition in § 335.3(c): ''*Travelers' diarrhea*. A subset of diarrhea occurring in travelers that is most commonly caused by an infectious agent.'' The agency is also proposing to add the following labeling indication in § 335.50(b)(1) for products containing bismuth subsalicylate: ''[* * * ''controls'' or ''relieves''] [* * * ''travelers' diarrhea''] * * *.'' Products may not be labeled with this claim until the monograph amendment process is completed and the agency publishes a final rule in a future issue of the **Federal Register**.

III. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). 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). Under the Regulatory Flexibility Act, if a rule has a significant economic impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation).

The agency tentatively concludes that this proposed rule is consistent with the principles set out in Executive Order 12866 and in these two statutes. The proposed rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order. The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for this proposed rule, because the proposed rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation. The current inflation adjusted statutory threshold is about $110 million.

The purpose of this proposed rule is to provide an additional (optional) claim for OTC antidiarrheal drug products containing bismuth subsalicylate. Manufacturers can add this claim to their labeling when ordering new product labeling to be in compliance with the OTC antidiarrheal drug products final monograph. Adding this claim might result in additional product sales but, in any case, is completely optional. Thus, this proposed rule will not impose a significant economic burden on affected entities. Therefore, the agency certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities. No further analysis is required under the Regulatory Flexibility Act (5 U.S.C. 605(b)).

The agency invites public comment regarding any substantial or significant economic impact that this proposed rule would have on OTC antidiarrheal drug products. Types of impact may include, but are not limited to, costs associated with relabeling or repackaging. Comments regarding the impact of this proposed rule should be accompanied by appropriate documentation. A period of 90 days from the date of publication of this proposed rule in the **Federal Register** will be provided for comments on this subject to be developed and submitted. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this proposed rule in the preamble to the final rule.

IV. Paperwork Reduction Act of 1995

FDA tentatively concludes that the labeling requirements proposed in this document 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, the proposed labeling statements are 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(a)).

V. Environmental Impact

The agency has determined under 21 CFR 25.31(a) 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.

VI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement has not been prepared.

VII. Request For Comments

Interested persons may submit written or electronic comments regarding this proposal and on the agency's economic impact determination to the Dockets Management Branch (*see* **ADDRESSES**) by (*see* **DATES**). Three copies of all written comments are to be submitted, except individuals may submit one 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Proposed Effective Date

The agency is proposing that any final rule that may issue based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

IX. References

The following references are on display in the Dockets Management Branch (*see* **ADDRESSES**) under Docket No. 78N–036D and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Comments No. SUP 8, SUP 13, SUP 14, LET 21, LET 23, PR 3, and MT 2.

2. Wilson, J. D. et al., editors, *Harrison's Principles of Internal Medicine*, 12th ed., McGraw-Hill, Inc., New York, NY, pp. 523–524, 1991.

List of Subjects in 21 CFR Part 335

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 part 335 be amended as follows:

PART 335—ANTIDIARRHEAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

■ 1. The authority citation for 21 CFR part 335 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

■ 2. Section 335.3 is amended by adding paragraph (c) to read as follows:

§ 335.3 Definitions.

* * * * *

(c) *Travelers' diarrhea*. A subset of diarrhea occurring in travelers that is most commonly caused by an infectious agent.

■ 3. Section 335.50 is amended by revising paragraph (b)(1) to read as follows:

§ 335.50 Labeling of antidiarrheal drug products.

* * * * *

(b) * * *

(1) *For products containing bismuth subsalicylate identified in § 335.10(a).* The labeling states [select one of the following: ''controls'' or ''relieves''] [select one or both of the following: ''diarrhea'' or ''travelers' diarrhea'']. If both ''diarrhea'' and ''traveler's diarrhea'' are selected, each shall be preceded by a bullet in accordance with § 201.66(b)(4) of this chapter and the heading ''Uses'' shall be used.

* * * * *

Dated: March 31, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–9381 Filed 4–16–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

31 CFR Part 103

RIN 1506–AA43

Financial Crimes Enforcement Network; Imposition of Special Measures Against the Country of Nauru

AGENCY: Financial Crimes Enforcement Network (FinCEN), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of the Treasury and FinCEN are issuing this proposed rule, pursuant to the provisions of section 311 of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), to impose ''special measures'' against Nauru. Nauru was previously designated as a country of primary money laundering concern pursuant to section 311 on December 20, 2002, a pre-requisite for the imposition of special measures.

DATES: Written comments may be submitted on or before May 19, 2003.

ADDRESSES: Commenters are encouraged to submit comments by electronic mail because paper mail in the Washington, DC, area may be delayed. Comments submitted by electronic mail may be sent to *regcomments@fincen.treas.gov* with the caption in the body of the text, ''Attention: Section 311 Special Measures Regulations.'' Comments may also be submitted by paper mail to FinCEN, P.O. Box 39, Vienna, VA 22183, Attn: Section 311 Special Measures Regulations. Comments should be sent by one method only. Comments may be inspected at FinCEN between 10 a.m. and 4 p.m. in the FinCEN Reading Room in Washington, DC. Persons wishing to inspect the comments submitted must request an appointment by telephoning (202) 354–6400 (not a toll-free number).

FOR FURTHER INFORMATION CONTACT: Office of the General Counsel, Department of the Treasury, (202) 622–1925; Office of the Assistant General Counsel for Banking and Finance (Treasury), (202) 622–0480; or the Office of Chief Counsel (FinCEN), (703) 905–3590 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

I. Background

On October 26, 2001, the President signed into law the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act) (Public Law 107–56) (the Act). Title III of the Act makes a number of amendments to the anti-money laundering provisions of the Bank Secrecy Act (BSA) that are codified in subchapter II of chapter 53 of title 31, United States Code. These amendments are intended to promote the prevention, detection, and prosecution of international money laundering and the financing of terrorism.

Section 311 of the Act added section 5318A to the BSA. Section 5318A gives the Secretary of the Treasury (Secretary) the authority to designate a foreign jurisdiction, institution(s), class(es) of transactions, or type(s) of account(s) as a ''primary money laundering concern'' and to impose certain ''special measures'' with respect to such jurisdiction, institution(s), class(es) of transactions, or type(s) of account(s). On December 20, 2002, the Secretary designated Nauru as a jurisdiction of primary money laundering concern pursuant to section 5318A.[1]

Section 5318A identifies the factors that the Secretary must consider and the agencies with which he must consult before designating a primary money laundering concern. Upon designation, section 5318A sets forth five potential special measures, the factors to be considered in selecting these measures, and the agencies with which the Secretary must consult before imposing special measures on the designee.

Section 5318A gives the Secretary the authority to bring additional and useful pressure on those jurisdictions and institutions that pose money laundering concerns to encourage them to eliminate the bases for these concerns. Through the imposition of various special measures, the Secretary can gain more information about the concerned

[1] 67 FR 78859 (December 26, 2002).