

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 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 beginning.

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

Reginald C. Matthews,
Manager, Airspace and Rules Division.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 335

[Docket No. 78N-0367]

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