

14 CFR Part 71

[Airspace Docket No. 95-AGL-5]

Modification of Class E Airspace; Devils Lake, ND**AGENCY:** Federal Aviation Administration (FAA), DOT.**ACTION:** Final rule.

SUMMARY: This action modifies the Class E5 airspace near Devils Lake, ND. Based on the results of an airspace review the existing geographic size of the E5 airspace area was found to be insufficient to accommodate existing instrument approach procedures to Devils Lake Municipal Airport, Devils Lake, ND. The intended effect of this action is to provide segregation of aircraft using instrument approach procedures in instrument conditions from other aircraft operating in visual weather conditions. The area will be depicted on aeronautical charts to provide a reference for pilots operating in Visual Flight Rule (VFR) conditions.

EFFECTIVE DATE: 0901 UTC, November 9, 1995.

FOR FURTHER INFORMATION CONTACT: Angeline Perri, Air Traffic Division, System Management Branch, AGL-530, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (708) 294-7571.

SUPPLEMENTARY INFORMATION:**History**

On June 9, 1995, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) to modify the Class E5 airspace near Devils Lake, ND (60 FR 30479).

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9B dated July 18, 1994, and effective September 16, 1994, which is incorporated by reference in CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) modifies the Class E airspace area near Devils Lake, ND. Based on the results of an airspace review the geographic size of the E5 airspace area was found to be insufficient to

accommodate existing instrument approach procedures to Devils Lake Municipal Airport, Devils Lake, ND. The intended effect of this action is to provide segregation of aircraft using instrument approach procedures in instrument conditions from other aircraft operating in visual weather conditions. The area will be depicted on aeronautical charts to provide a reference for pilots operating in VFR conditions.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 part 71 continues to read as follows:

Authority: 49 U.S.C. 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9B, Airspace Designations and Reporting Points, dated July 18, 1994, and effective September 16, 1994, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AGL ND E5 Devils Lake, ND [Revised]

Devils Lake Municipal Airport, ND
(Lat. 48°06'51" N, long. 98°54'32" W)
Devils Lake VORTAC
(Lat. 48°06'48" N, long. 98°54'29" W)

That airspace extending upward from 700 feet above the surface within an 8.7-mile radius of the Devils Lake Municipal Airport and that airspace extending upward from 1,200 feet above the surface within a 22-mile radius of the Devils Lake VORTAC.

* * * * *

Issued in Des Plaines, Illinois, on July 27, 1995.

Maureen Woods,

Acting Manager, Air Traffic Division.

[FR Doc. 95-20266 Filed 8-15-95; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TREASURY**Customs Service****19 CFR Part 19****Duty-Free Stores****CFR Correction**

In title 19 of the Code of Federal Regulations, parts 1 to 140, revised as of July 1, 1995, § 19.5 appearing on page 235 should be removed and reserved.

BILLING CODE 1505-01-D

SOCIAL SECURITY ADMINISTRATION**20 CFR Parts 404 and 422****RIN 0960-AD70****Wage Reports and Pension Information**

AGENCY: Social Security Administration.

ACTION: Final rules.

SUMMARY: We are updating our rules on the need for and use of employer identification numbers and on processing reports of wages provided annually by employers to the Social Security Administration (SSA). In addition, we are adding to our rules the procedures we have for maintaining and providing information we receive from employers on deferred vested pension benefits.

EFFECTIVE DATE: These rules are effective August 16, 1995.

ADDRESSES: Organizations and individuals desiring to submit comments on the information collection requirements under “Paperwork Reduction Act” should submit them to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, Room 3208, Washington, DC 20503, Attention: Desk Officer for SSA.

FOR FURTHER INFORMATION CONTACT: Jack Schamberger, Legal Assistant, 3-B-1 Operations Building, 6401 Security Boulevard, Baltimore, MD 21235, (410) 965-8471.

SUPPLEMENTARY INFORMATION:**Employer Identification Numbers**

Pursuant to section 205(c)(2)(A) of the Social Security Act (the Act), SSA maintains a record of the wages and self-employment income of each individual. The record includes earnings covered under title II of the Act, earnings covered under title XVIII of the Act, and earnings not covered under the Act. The record is identified by the individual's social security number. Wages posted to an individual's record are based on wage reports submitted to SSA and the Internal Revenue Service (IRS) by employers. IRS regulations at 26 CFR 31.6011(a)-1 require an employer to file employment tax returns with IRS each year and IRS regulations at 26 CFR 31.6051-2 and 31.6091-1(d) require an employer to file wage reports with SSA each year. These requirements are also explained on wage reporting forms and in related instructions issued by SSA and IRS. To help account for these returns and reports, IRS assigns an employer identification number (EIN) to every employer. However, SSA will assign a special identification number to one or more political subdivisions of a State which submits a modification to its coverage agreement under section 218 of the Act. These numbers are assigned only for State bookkeeping purposes unless coverage is extended to periods prior to 1987. Then, the special number will be assigned and used for reporting the pre-1987 wages to SSA. The special number will also be assigned to an interstate instrumentality if pre-1987 coverage is obtained.

Annual Wage Reporting

Section 232 of the Act was added by section 8 of Public Law 94-202. Section 8 is cited as the "Combined Old-Age, Survivors, and Disability Insurance-Income Tax Reporting Amendments of 1975." Section 232, as amended by section 107 of Public Law 103-296, provides authority for the Secretary of the Treasury to make available to the Commissioner of Social Security such documents that are agreed upon as being necessary for processing information contained in returns required by the Internal Revenue Code and by IRS regulations. Under this authority and Public Law 94-455 and 95-216, SSA and IRS have entered into an Agreement governing the manner in which employer wage reports will be processed. Included in this process are the wage reports which employers are required to file annually with SSA. As required by IRS regulations at 26 CFR 301.6011-2, employers who file 250 or

more wage reports per year must file them on magnetic media, unless the requirement is waived by IRS. These regulations reflect these requirements for filing annual wage reports with SSA and explain how SSA will process the reports and reconcile reporting errors with IRS, employees, and employers.

Incorrect Wage Reports

We are also consolidating §§ 422.115 and 422.120 to include in one section (§ 422.120) our current procedures for processing wage reports submitted to us by employers that do not include a worker's social security number or include an incorrect name or number. The existing regulations provide that we will first contact the employer for the missing information or correction. However, in this revised regulation, we state our current procedure which is to attempt to contact the employee first. Additionally, we provide that we may return to the employer a wage report submittal if 90 percent or more of the wage reports in that submittal are unidentified or incorrectly identified. We also explain in revised § 422.120 that we will inform IRS of all wage reports filed with SSA that do not include the required social security numbers. IRS may then assess the employer a penalty for erroneous report filing, pursuant to the authority provided in section 6721 of the Internal Revenue Code.

Pension Plan Information

Under section 6057 of the Internal Revenue Code, certain private pension plan administrators must file with the IRS annual reports that identify individuals who separated from plan coverage during the year and still have a right to future retirement benefits. In addition, this provision of the Internal Revenue Code, as amended by section 108(h)(5) of Public Law 103-296, provides for transmitting copies of the annual reports to the Commissioner of Social Security. Then SSA transcribes the reports onto an electronic record for the purpose of maintaining the pension information which SSA must provide to specified individuals, as explained below.

Section 1131 of the Act, as amended by section 108(b)(11) of Public Law 103-296, requires that whenever the Commissioner of Social Security is requested to do so, or whenever he or she makes a finding of fact and a decision as to the entitlement of an individual to social security or medicare benefits under title II of the Act, he or she must transmit to the individual any information, as reported by the employer, regarding any deferred vested

benefits under a private pension plan. In these rules, we explain how we administer this provision.

Final Rules

On August 30, 1994, we published proposed rules in the **Federal Register** at 59 FR 44674 with a 60-day comment period. We received no comments on these proposed rules. We are, therefore, publishing the proposed rules essentially unchanged as final rules.

Regulatory Procedures*Executive Order 12866*

We have consulted with the Office of Management and Budget (OMB) and determined that these rules do not meet the criteria for a significant regulatory action under Executive Order 12866. Thus, they were not subject to OMB review.

Regulatory Flexibility Act

We certify that these final rules will not have a significant economic impact on a substantial number of small entities because the procedures stated in these rules are already in effect without having caused a significant impact. Therefore, a regulatory flexibility analysis as provided in Public Law 96-354, the Regulatory Flexibility Act, is not required.

Paperwork Reduction Act

These final rules contain reporting requirements in §§ 422.114 (e) and (f) and 422.120(a). We would normally seek approval of these requirements, under the Paperwork Reduction Act, from OMB. We are not doing so in this situation because we already have clearance from OMB to collect this information using forms SSA-L93, 95 and 97 (OMB No. 0960-0432) and form SSA-2765 (OMB No. 0960-0471).

There is also a reporting requirement in § 422.122, which deals with information on deferred vested pension benefits. As required by section 2(a) of the Paperwork Reduction Act of 1980, 44 U.S.C. 3504(h), we have submitted a copy to OMB for its review of this information collection requirement. Other organizations and individuals desiring to submit comments on these information collection requirements should direct them to the address shown in **ADDRESSES**.

Public reporting burden for this collection of information is estimated to average 30 minutes per response. This includes the time it will take to understand what is needed, gather the necessary facts, and provide the information. We expect that annually there will be 2,280 requesters of pension plan information. Therefore, the annual

reporting burden is expected to be 1,140 hours. If you have any comments or suggestions on this estimate, write to the Social Security Administration, ATTN: Reports Clearance Officer, 1-A-21 Operations Building, Baltimore, MD 21235, and to the Office of Management and Budget, Paperwork Reduction Project (0960-NEW), Washington, DC 20503.

(Catalog of Federal Domestic Assistance Program Nos. 96.001 Social Security-Disability Insurance; 96.002 Social Security-Retirement Insurance; 96.004 Social Security-Survivors Insurance.)

List of Subjects

20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors, and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

20 CFR Part 422

Administrative practice and procedure, Freedom of information, Organization and functions (Government agencies), Social security.

Dated: July 27, 1995.

Shirley Chater,
Commissioner of Social Security.

For the reasons set out in the preamble, we are amending subpart M of part 404 and subpart B of part 422 of 20 CFR chapter III as follows:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950—)

Subpart M—[Amended]

1. The authority citation for subpart M of part 404 continues to read as follows:

Authority: Secs. 205, 210, 218, and 1102 of the Social Security Act; 42 U.S.C. 405, 410, 418, and 1302; sec. 12110 of Pub. L. 99-272, 100 Stat. 287; sec. 9002 of Pub. L. 99-509, 100 Stat. 1970.

2. Section 404.1220 is amended by revising paragraphs (a) and (e) to read as follows:

§ 404.1220 Identification numbers.

(a) *State and local government.* When a State submits a modification to its agreement under section 218 of the Act, SSA will assign a special identification number to each political subdivision included in that modification. SSA will inform the State of the special identification number(s) by sending a Form SSA-214-CD, "Notice of Identifying Number," to the State. These numbers are assigned only for State bookkeeping purposes unless coverage is extended to periods prior to 1987.

Then, the special number will be assigned and used for reporting the pre-1987 wages to SSA. The special number will also be assigned to an interstate instrumentality if pre-1987 coverage is obtained and SSA will send a Form SSA-214-CD to the interstate instrumentality to notify it of the number assigned.

* * * * *

(e) *Use.* For wages paid prior to 1987, the employer shall show the appropriate SSA-issued identifying number, including any coverage group or payroll record unit number, on records, reports, returns, and claims to report wages, adjustments, and contributions.

PART 422—ORGANIZATION AND PROCEDURES

Subpart B—[Amended]

1. The authority citation for subpart B of part 422 is revised to read as follows:

Authority: Secs. 205, 232, 1102, 1131, and 1143 of the Social Security Act (42 U.S.C. 405, 432, 1302, 1320b-1, and 1320b-13).

2. Section 422.112 is revised to read as follows:

§ 422.112 Employer identification numbers.

(a) *General.* Most employers are required by section 6109 of the Internal Revenue Code and by Internal Revenue Service (IRS) regulations at 26 CFR 31.6011(b)-1 to obtain an employer identification number (EIN) and to include it on wage reports filed with SSA. A sole proprietor who does not pay wages to one or more employees or who is not required to file any pension or excise tax return is not subject to this requirement. To apply for an EIN, employers file Form SS-4, "Application for Employer Identification Number," with the IRS. For the convenience of employers, Form SS-4 is available at all SSA and IRS offices. Household employers, agricultural employers, and domestic corporations which elect social security coverage for employees of foreign subsidiaries who are citizens or residents of the U.S. may be assigned an EIN by IRS without filing an SS-4.

(b) *State and local governments.* To facilitate a State's bookkeeping, SSA will assign a special identification number to each political subdivision included in a modification to the State's agreement under section 218 of the Act. These numbers are not used for reporting purposes unless coverage is extended to periods prior to 1987. Then, the special number will be assigned and used for reporting the pre-1987 wages to SSA. This special number will also be assigned to an interstate instrumentality

if pre-1987 coverage is obtained. SSA will inform the appropriate State or interstate instrumentality official of the assigned number by sending a Form SSA-214-CD, "Notice of Identifying Number."

3. A new § 422.114 is added to read as follows:

§ 422.114 Annual wage reporting process.

(a) *General.* Under the authority of section 232 of the Act, SSA and IRS have entered into an agreement that sets forth the manner by which SSA and IRS will ensure that the processing of employee wage reports is effective and efficient. Under this agreement, employers are instructed by IRS to file annual wage reports with SSA on paper Forms W-2, "Wage and Tax Statement," and Forms W-3, "Transmittal of Income and Tax Statements," or equivalent W-2 and W-3 magnetic media reports. Special versions of these forms for Puerto Rico, Guam, American Samoa, the Virgin Islands, and the Commonwealth of the Northern Mariana Islands are also filed with SSA. SSA processes all wage reporting forms for updating to SSA's earnings records and IRS tax records, identifies employer reporting errors and untimely filed forms for IRS penalty assessment action, and takes action to correct any reporting errors identified, except as provided in paragraph (c) of this section. SSA also processes Forms W-3c, "Transmittal of Corrected Income Tax Statements," and W-2c, "Statement of Corrected Income and Tax Amounts" (and their magnetic media equivalents) that employers are required to file with SSA when certain previous reporting errors are discovered.

(b) *Magnetic media reporting requirements.* Under IRS regulations at 26 CFR 301.6011-2, employers who file 250 or more W-2 wage reports per year must file them on magnetic media in accordance with requirements provided in SSA publications, unless IRS grants the employer a waiver. Basic SSA requirements are set out in SSA's Technical Instruction Bulletin No. 4, "Magnetic Media Reporting." Special filing requirements for U.S. territorial employers are set out in SSA Technical Instruction Bulletins No. 5 (Puerto Rico), No. 6 (Virgin Islands), and No. 7 (Guam and American Samoa). At the end of each year, SSA mails these technical instructions to employers (or third parties who file wage reports on their behalf) for their use in filing wage reports for that year.

(c) *Processing late and incorrect magnetic media wage transmittals.* If an employer's transmittal of magnetic media wage reports is received by SSA after the filing due date, SSA will notify

IRS of the late filing so that IRS can decide whether to assess penalties for late filing, pursuant to section 6721 of the Internal Revenue Code. If reports do not meet SSA processing requirements (unprocessable reports) or are out of balance on critical money amounts, SSA will return them to the employer to correct and resubmit. In addition, beginning with wage reports filed for tax year 1993, if 90 percent or more of an employer's magnetic media wage reports have no social security numbers or incorrect employee names or social security numbers so that SSA is unable to credit their wages to its records, SSA will not attempt to correct the errors, but will instead return the reports to the employer to correct and resubmit (see also § 422.120(b)). An employer must correct and resubmit incorrect and unprocessable magnetic media wage reports to SSA within 45 days from the date of the letter sent with the returned report. Upon request, SSA may grant the employer a 15-day extension of the 45-day period. If an employer does not submit corrected reports to SSA within the 45-day (or, if extended by SSA, 60-day) period, SSA will notify IRS of the late filing so that IRS can decide whether to assess a penalty. If an employer timely resubmits the reports as corrected magnetic media reports, but they are unprocessable or out of balance on W-2 money totals, SSA will return the resubmitted reports for the second and last time for the employer to correct and return to SSA. SSA will enclose with the resubmitted and returned forms a letter informing the employer that he or she must correct and return the reports to SSA within 45 days or be subject to IRS penalties for late filing.

(d) *Paper form reporting requirements.* The format and wage reporting instructions for paper forms are determined jointly by IRS and SSA. Basic instructions on how to complete the forms and file them with SSA are provided in IRS forms materials available to the public. In addition, SSA provides standards for employers (or third parties who file wage reports for them) to follow in producing completed reporting forms from computer software; these standards appear in SSA publication, "Software Specifications and Edits for Annual Wage Reporting." Requests for this publication should be sent to: Social Security Administration, Office of Financial Policy and Operations, Attention: AWR Software Standards Project, P.O. Box 17195, Baltimore, MD 21235.

(e) *Processing late and incorrect paper form reports.* If SSA receives paper form

wage reports after the due date, SSA will notify IRS of the late filing so that IRS can decide whether to assess penalties for late filing, pursuant to section 6721 of the Internal Revenue Code. SSA will ask an employer to provide replacement forms for illegible, incomplete, or clearly erroneous paper reporting forms, or will ask the employer to provide information necessary to process the reports without having to resubmit corrected forms. (For wage reports where earnings are reported without a social security number or with an incorrect name or social security number, see § 422.120.) If an employer fails to provide legible, complete, and correct W-2 reports within 45 days, SSA may identify the employers to IRS for assessment of employer reporting penalties.

(f) *Reconciliation of wage reporting errors.* After SSA processes wage reports, it matches them with the information provided by employers to the IRS on Forms 941, "Employer's Quarterly Federal Tax Return," for that tax year. Based upon this match, if the total social security or medicare wages reported to SSA for employees is less than the totals reported to IRS, SSA will write to the employer and request corrected reports or an explanation for the discrepancy. If the total social security or medicare wages reported to SSA for employees is more than the totals reported to IRS, IRS will resolve the difference with the employer. If the employer fails to provide SSA with corrected reports or information that shows the wage reports filed with SSA are correct, SSA will ask IRS to investigate the employer's wage and tax reports to resolve the discrepancy and to assess any appropriate reporting penalties.

§ 422.115 [Removed]

4. Section 422.115 is removed.
5. Section 422.120 is revised to read as follows:

§ 422.120 Earnings reported without a social security number or with an incorrect employee name or social security number.

(a) *Correcting an earnings report.* If an employer reports an employee's wages to SSA without the employee's social security number or with a different employee name or social security number than shown in SSA's records for him or her, SSA will write to the employee at the address shown on the wage report and request the missing or corrected information. If the wage report does not show the employee's address or shows an incomplete address, SSA

will write to the employer and request the missing or corrected employee information. SSA notifies IRS of all wage reports filed without employee social security numbers so that IRS can decide whether to assess penalties for erroneous filing, pursuant to section 6721 of the Internal Revenue Code. If an individual reports self-employment income to IRS without a social security number or with a different name or social security number than shown in SSA's records, SSA will write to the individual and request the missing or corrected information. If the employer, employee, or self-employed individual does not provide the missing or corrected report information in response to SSA's request, the wages or self-employment income cannot be identified and credited to the proper individual's earnings records. In such cases, the information is maintained in a "Suspense File" of uncredited earnings. Subsequently, if identifying information is provided to SSA for an individual whose report is recorded in the Suspense File, the wages or self-employment income then may be credited to his or her earnings record.

(b) *Returning incorrect reports.* SSA may return to the filer, unprocessed, an employer's annual wage report submittal if 90 percent or more of the wage reports in that submittal are unidentified or incorrectly identified. In such instances, SSA will advise the filer to return corrected wage reports within 45 days to avoid any possible IRS penalty assessment for failing to file correct reports timely with SSA. (See also § 422.114(c).) Upon request, SSA may grant the employer a 15-day extension of the 45-day period.

5. A new § 422.122 is added to read as follows:

§ 422.122 Information on deferred vested pension benefits.

(a) *Claimants for benefits.* Each month, SSA checks the name and social security number of each new claimant for social security benefits or for hospital insurance coverage to see whether the claimant is listed in SSA's electronic pension benefit record. This record contains information received from IRS on individuals for whom private pension plan administrators have reported to IRS, as required by section 6057 of the Internal Revenue Code, as possibly having a right to future retirement benefits under the plan. SSA sends a notice to each new claimant for whom it has pension benefit information, as required by

section 1131 of the Act. If the claimant filed for the lump-sum death payment on the social security account of a relative, SSA sends the claimant the pension information on the deceased individual. In either case, SSA sends the notice after it has made a decision on the claim for benefits. The notice shows the type, payment frequency, and amount of pension benefit, as well as the name and address of the plan administrator as reported to the IRS. This information can then be used by the claimant to claim any pension benefits still due from the pension plan.

(b) *Requesting deferred vested pension benefit information from SSA files.* Section 1131 of the Act also requires SSA to provide available pension benefit information on request. SSA will provide this pension benefit information only to the individual who has the pension coverage (or a legal guardian or parent, in the case of a minor, on the individual's behalf). However, if the individual is deceased, the information may be provided to someone who would be eligible for any underpayment of benefits that might be due the individual under section 204(d) of the Act. All requests for such information must be in writing and should contain the following information: the individual's name, social security number, date of birth, and any information the requestor may have concerning the name of the pension plan involved and the month and year coverage under the plan ended, the name and address of the person to whom the information is to be sent; and the requester's signature under the following statement: "I am the individual to whom the information applies (or "I am related to the individual as his or her _____"). I know that if I make any representation which I know is false to obtain information from Social Security records, I could be punished by a fine or imprisonment or both." Such requests should be sent to: Social Security Administration, Office of Central Records Operations, P.O. Box 17055, Baltimore, Maryland 21235.

[FR Doc. 95-19501 Filed 8-15-95; 8:45 am]

BILLING CODE 4190-29-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. 77N-334S]

RIN 0905-AA06

Topical Drug Products for Over-the-Counter Human Use; Products for the Prevention of Swimmer's Ear and for the Drying of Water-Clogged Ears; Partial Stay of Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; partial stay of regulation.

SUMMARY: The Food and Drug Administration (FDA) is staying part of a final rule that established that any over-the-counter (OTC) topical otic drug products for the prevention of swimmer's ear or for the drying of water-clogged ears is not generally recognized as safe and effective and is misbranded. This action, which is being taken in response to new clinical data and a petition for stay of action, applies only to topical otic drug products for the drying of water-clogged ears. This action is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: June 22, 1995.

FOR FURTHER INFORMATION CONTACT:

William E. Gilbertson, Center for Drug Evaluation and Research (HFD-810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5000.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 8, 1986 (51 FR 28656), the agency published a final rule establishing conditions under which OTC topical otic drug products are generally recognized as safe and effective. That final rule applied only to earwax removal aids. Products for the prevention of swimmer's ear and for the drying of water-clogged ears were not considered by the agency at that time.

In the **Federal Register** of February 15, 1995 (60 FR 8916), the agency declared that OTC drug products containing active ingredients for the prevention of swimmer's ear or for the drying of water-clogged ears were new drugs under section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)). To be marketed, such products would require an application or abbreviated application approved under section 505

of the act (21 U.S.C. 355) and 21 CFR part 314. In the absence of an approved application, products for this use also would be misbranded under section 502 of the act (21 U.S.C. 352). The agency also stated that, in appropriate circumstances, a citizen petition to establish a monograph may be submitted under § 10.30 (21 CFR 10.30) in lieu of an application.

Subsequently, Buc Levitt & Beardsley, on behalf of Del Pharmaceuticals, Inc., filed a citizen petition (Ref. 1) to: (1) Permit the marketing of 95 percent isopropyl alcohol in 5 percent anhydrous glycerin for the drying of water-clogged ears, and (2) remove glycerin, anhydrous glycerin, and isopropyl alcohol from the list of active ingredients in § 310.545(a)(15)(ii) (21 CFR 310.545(a)(15)(ii)). This petition included the results of a double-blinded, 3-arm parallel study to evaluate the efficacy and tolerability of isopropyl alcohol in drying water-clogged ears in 90 adult volunteers. Buc Levitt & Beardsley, on behalf of Del Pharmaceuticals, Inc., also filed a petition (Ref. 2), pursuant to 21 CFR 10.35, requesting a stay of the August 15, 1995, effective date of the final rule to allow time for the agency to review the results of the new study.

The agency reviewed the results of this study and determined that 95 percent isopropyl alcohol in a 5 percent anhydrous glycerin base is safe and effective for OTC use for drying water-clogged ears. The agency's detailed comments and evaluations of this study are on file in the Dockets Management Branch (Ref. 3).

On June 22, 1995, FDA agreed to stay the effective date of the final rule for OTC swimmer's ear and the drying of water-clogged ear drug products (Ref. 4). The agency intends to propose to amend the final monograph for OTC topical otic drug products to include conditions under which drug products for the drying of water-clogged ears are generally recognized as safe and effective and not misbranded.

The agency has determined that the stay of action applies only to topical otic drug products for the drying of water-clogged ears. The new study did not involve the prevention of swimmer's ear. Therefore, the August 15, 1995, effective date for § 310.545(a)(15)(ii) remains in effect for topical otic drug products for the prevention of swimmer's ear. The August 15, 1995, effective date is stayed only for topical otic drug products for the drying of water-clogged ears.