Manager, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; *telephone:* (816) 329–4130; *fax:* (816) 329–4090. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(h) Refer to MCAI Federal Republic of Germany Luftfahrt-Bundesamt AD D–2006–060, dated March 6, 2006; and DG Flugzeugbau GmbH Technical Note No. 843–24, dated January 31, 2006.

Material Incorporated by Reference

(i) You must use DG Flugzeugbau GmbH Technical Note No. 843–24, dated January 31, 2006; DG Flugzeugbau GmbH Working instruction No. 1, dated January 23, 2006; DG Flugzeugbau GmbH Working instruction No. 2, dated January 30, 2006; DG Flugzeugbau GmbH Drawing 5M210, Spindle drive Stross BSA 10 assembly, revised May 19, 2006; and DG Flugzeugbau GmbH Drawing 5M211, Spindle drive Stross BSA 10 assembly with strengthened fork 8M233''f'', dated January 23, 2006, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact DG Flugzeugbau GmbH, Im Schollengarten 20, D–76646 Bruchsal 4, Federal Republic of Germany.

(3) You may review copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Kansas City, Missouri, on December 20, 2007.

John R. Colomy,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E7–25212 Filed 1–2–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 208, and 209

[Docket No. 2003N–0342]

RIN 0910–AC35

Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing an interim final rule to codify the provisions of the proposed rule entitled ''Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products'' (69 FR 21778, April 22, 2004) (the toll-free number proposed rule or proposed rule) that, under the Food and Drug Administration Amendments Act of 2007 (FDAAA), became effective by operation of law on January 1, 2008. This interim final rule requires the addition of a statement on the labeling of certain human drug products for which an application is approved under the Federal Food, Drug, and Cosmetic Act (the act). The added statement includes a toll-free number and advises that the number is to be used only for reporting side effects and is not intended for medical advice (the side effects statement). As mandated by FDAAA, this interim final rule does not apply to over-the-counter drug products approved as new drugs under the act if the product packaging includes a manufacturer's or distributor's toll-free number for reporting complaints.

DATES: *Effective Date*: This rule is effective January 1, 2008.

Compliance Date: The agency anticipates that affected entities, including manufacturers, authorized dispensers, and pharmacies, will need time to update labeling and systems to comply with the new requirements. Therefore, FDA intends to exercise its enforcement discretion and not take enforcement actions with regard to these regulations until January 1, 2009.

FOR FURTHER INFORMATION CONTACT: Carol Drew, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

On September 27, 2007, the President signed into law FDAAA (Public Law 110–85). Among other things, FDAAA reauthorized the Best Pharmaceuticals for Children Act (BPCA). When enacted in 2001, the BPCA (Public Law 107–109) directed FDA to issue a final rule requiring the labeling of each human drug product for which an application is approved under section 505 of the act (21 U.S.C. 355) to include: (1) A toll-free number maintained by FDA for the purpose of receiving reports of adverse events regarding drugs and (2) a statement that the number is to be used for reporting purposes only, not to receive medical advice. Collectively, we refer to the toll-free number and reporting statement as the ''side effects statement.'' The BPCA stated that the final rule must reach the broadest consumer audience and minimize the cost to the pharmacy profession.

As required, FDA issued a proposed rule entitled ''Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products'' (69 FR 21778, April 22, 2004). FDA received 22 comments on this proposed rule and was in the process of analyzing the comments and conducting research on consumer comprehension of the side effects statement when FDAAA was enacted (see section IV of this document).

II. FDAAA Requirements

Section 502(f) of FDAAA states that ''the proposed rule * * * 'Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products' * * * shall take effect on January 1, 2008,'' unless FDA issues a final rule before that date.

FDAAA mandates one change to the proposed rule. As described in section III of this document, section 502(f)(2) of FDAAA states that the toll-free number proposed rule shall not apply to over-the-counter (OTC) drugs marketed with an application approved under section 505 of the act (application OTC drug products) if these application OTC drug products meet certain labeling requirements. (Neither the BPCA, the proposed rule, nor this interim final rule addresses OTC drugs marketed *without* approved applications.)

Because the agency's rulemaking process is ongoing, for the reasons explained in section IV of this document, this interim rule codifies the provisions of the proposed rule as modified by FDAAA. As mandated by FDAAA, these provisions came into effect on January 1, 2008. The agency is publishing this interim final rule to codify the modified toll-free number proposed rule that has now come into effect.

III. Description of the Interim Final Rule

Consistent with the mandates of the BPCA, FDA proposed to require that the side effects statement be included in FDA-approved Medication Guides for drug products approved under section 505 of the act. We also proposed that the side effects statement be distributed with each prescription drug product approved under section 505 of the act and dispensed to consumers by pharmacies and authorized dispensers in an outpatient setting. In addition, as described in the toll-free number proposed rule, FDA interpreted the BPCA to apply to application OTC drug products. Accordingly, FDA also proposed to require the side effects statement in the labeling for application OTC drug products.

Section 502(f)(2) of FDAAA states that the proposed rule shall not apply to a drug: (1) For which an application is approved under section 505 of the act; (2) that is not described under section 503(b)(1) of the act (21 U.S.C. 353(b)(1)); and (3) the packaging of which includes a toll-free number through which consumers can report complaints to the manufacturer or distributor of the drug. This provision means that the proposed rule as it has come into effect by operation of law in accordance with FDAAA does not apply to an application OTC drug product if the product's packaging includes a manufacturer's or distributor's toll-free number for reporting complaints. Accordingly, this interim final rule includes a modified § 201.66(c)(5)(vii) reflecting the change to the proposed rule mandated by FDAAA.

IV. Ongoing Research on the Side Effects Statement

FDA is in the process of conducting research on the wording of the side effects statement published in the toll-free number proposed rule. FDA initiated this research after reviewing the comments on the proposed rule. Among the reasons cited in these comments for testing the statement were: (1) To determine the best and most precise wording for the statement; (2) to evaluate consumer comprehension of the proposed statement; and (3) to address concerns that consumers who read the statement will mistakenly call FDA in search of medical advice.

FDA designed a two-part study in response to these comments. Part one consisted of focus groups held to narrow the field of potential statement alternatives. This research was completed in 2006 (OMB Control No. 0910–0497). The second part of this research is a labeling comprehension experiment to be conducted over the Internet (OMB Control No. 0910–0603). FDA plans to complete this research. Then, based on the results of the data collected from the research and the comments received on the proposed rule, the agency will determine whether to finalize this interim final rule as published or to publish a final rule that amends this interim final rule. The effective date and implementation schedule for the final rule will be designed to minimize the burden of any additional regulatory changes for affected entities who must comply with this interim final rule.

V. Legal Authority

Section 502(f) of FDAAA states that the toll-free number proposed rule shall take effect on January 1, 2008, unless the agency publishes a final rule prior to that date. FDA determined that the research being undertaken to inform the proposed side effects statement could not be completed in time for FDA to publish a final rule prior to January 1, 2008, and that this research needed to be completed for the agency to respond fully to the comments received on the toll-free number proposed rule. Therefore, FDA did not publish a final rule before January 1, 2008, and the toll-free number proposed rule, as modified by FDAAA, came into effect by operation of law on that date.

FDA has received comments on the proposed rule addressing issues including the scope of the rule, the content and presentation of the side effects statement, the reporting provisions, the costs and benefits of the rule, implementation of the rule, and compliance with it. As part of the final rulemaking that the agency will undertake after completing the research on the side effects statement (see section IV in this document), FDA will consider and address all comments submitted to the docket for the toll-free number proposed rule.

VI. Effective Date/Compliance Date

As mandated by FDAAA, the effective date of the interim final rule is January 1, 2008. In the preamble to the toll-free number proposed rule, the agency proposed that all manufacturers, dispensers and pharmacies subject to the rule be in compliance not more than 1 year after the effective date of the final rule. FDA explained that the agency anticipated these entities would require time to update labeling and systems to comply with the new requirements.

FDAAA does not address timing needs for affected entities to come into compliance with the rule. The only change FDAAA makes to the agency's proposal is to limit the scope of the proposed rule to make the rule inapplicable to certain application OTC drug products. Accordingly, FDA concludes that FDAAA was not intended to make any other changes to the agency's proposal, including with regard to addressing the anticipated needs of affected entities for time to come into compliance with the rule.

FDA continues to anticipate that affected entities, including manufacturers of drug products, authorized dispensers, and pharmacies, will need time to update labeling and systems to comply with the new requirements. Therefore, consistent with the agency's proposal, the agency intends to exercise its enforcement discretion with regard to these regulations until January 1, 2009. That is, the agency does not intend to take enforcement action with regard to this interim final rule before that date.

List of Subjects

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 208

Labeling, Prescription drugs, Reporting and recordkeeping requirements.

21 CFR Part 209

Authorized dispensers, Drugs, Pharmacies, Prescription drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR Chapter I is amended as follows:

PART 201—LABELING

■ 1. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

■ 2. Amend § 201.66 by adding two sentences at the end of paragraph (c)(5)(vii) to read as follows:

§ 201.66 Format and content requirements for over-the-counter (OTC) drug product labeling.

* * * * *

(c) * * *

(5) * * *

(vii) * * * For all OTC drug products under an approved drug application whose packaging does not include a toll-free number through which consumers can report complaints to the manufacturer or distributor of the drug product, the following text shall

immediately follow the subheading: ''[Bullet] side effects occur. You may report side effects to FDA at 1–800–FDA–1088.'' The telephone number must appear in a minimum 6–point bold letter height or type size.

* * * * *

PART 208—MEDICATION GUIDES FOR PRESCRIPTION DRUG PRODUCTS

■ 3. The authority citation for 21 CFR part 208 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360, 371, 374; 42 U.S.C. 262.

■ 4. Amend § 208.20 by adding paragraph (b)(7)(iii) to read as follows:

§ 208.20 Content and format of a Medication Guide.

* * * * *

(b) * * *

(7) * * *

(iii) For drug products approved under section 505 of the act, the following verbatim statement: ''Call your doctor for medical advice about side effects. You may report side effects to FDA at 1–800–FDA–1088.''

* * * * *

■ 5. Add part 209 to read as follows:

PART 209—REQUIREMENT FOR AUTHORIZED DISPENSERS AND PHARMACIES TO DISTRIBUTE A SIDE EFFECTS STATEMENT

Subpart A—General Provisions

Subpart B—Requirements

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 371; 42 U.S.C. 241.

Subpart A—General Provisions

§ 209.1 Scope and purpose.

(a) This part sets forth requirements for human prescription drug products approved under section 505 of the Federal Food, Drug, and Cosmetic Act and dispensed by authorized dispensers and pharmacies to consumers. This part requires distribution of a side effects statement and applies to new and refill prescriptions. This part is not intended to apply to authorized dispensers dispensing or administering prescription drug products to inpatients in a hospital or health care facility under an order of a licensed practitioner, or as part of supervised home health care.

(b) The purpose of providing the side effects statement is to enable consumers to report side effects of prescription drug products to FDA.

§ 209.2 Definitions.

For the purposes of this part, the following definitions apply:

Act means the Federal Food, Drug, and Cosmetic Act (sections 201–907 (21 U.S.C. 301–397)).

Authorized dispenser means an individual licensed, registered, or otherwise permitted by the jurisdiction in which the individual practices to provide drug products on prescription in the course of professional practice.

Consumer medication information means written information voluntarily provided to consumers by dispensing pharmacists as part of patient medication counseling activities.

Medication Guide means FDA-approved patient labeling conforming to the specifications set forth in part 208 of this chapter and other applicable regulations.

Pharmacy includes, but is not limited to, a retail, mail order, Internet, hospital, university, or clinic pharmacy, or a public health agency, regularly and lawfully engaged in dispensing prescription drugs.

Side effects statement means the following verbatim statement: ''Call your doctor for medical advice about side effects. You may report side effects to FDA at 1–800–FDA–1088.''

Subpart B—Requirements

§ 209.10 Content and format of the side effects statement.

(a) *Content.* The side effects statement provided with each prescription drug product approved under section 505 of the act must read: ''Call your doctor for medical advice about side effects. You may report side effects to FDA at 1–800–FDA–1088.''

(b) *Format.* The side effects statement must be in a single, clear, easy-to-read type style. The letter height or type size used for the side effects statement in accordance with paragraphs (b)(1) and (b)(2) of § 209.11 must be no smaller than 6 points (1 point = 0.0138 inch). The letter height or type size for the side effects statement under paragraphs (b)(3), (b)(4), and (b)(5) of § 209.11 must be no smaller than 10 points.

§ 209.11 Dispensing and distributing the side effects statement.

(a) Each authorized dispenser or pharmacy must distribute the side effects statement with each prescription drug product approved under section 505 of the act and dispensed. The side effects statement must be distributed with new and refill prescriptions.

(b) An authorized dispenser or pharmacy must choose one or more of the following options to distribute the side effects statement:

(1) Distribute the side effects statement on a sticker attached to the unit package, vial, or container of the drug product;

(2) Distribute the side effects statement on a preprinted pharmacy prescription vial cap;

(3) Distribute the side effects statement on a separate sheet of paper;

(4) Distribute the side effects statement in consumer medication information; or

(5) Distribute the appropriate FDA-approved Medication Guide that contains the side effects statement.

Dated: December 21, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–25426 Filed 1–2–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–1385–F2]

RIN 0938–AO65

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Delay of the Date of Applicability of the Revised Anti-Markup Provisions for Certain Services Furnished in Certain Locations (§ 414.50)

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule delays until January 1, 2009 the applicability of the anti-markup provisions in § 414.50, as revised at 72 FR 66222, except with respect to the technical component of a purchased diagnostic test and with respect to any anatomic pathology diagnostic testing services furnished in space that: Is utilized by a physician group practice as a ''centralized building'' (as defined at § 411.351 of this chapter) for purposes of complying with the physician self-referral rules; and does not qualify as a ''same building'' under § 411.355(b)(2)(i) of this chapter.

DATES: The provisions of this final rule are effective January 1, 2008. However,