Administrative Procedure Act

Prior notice and an opportunity for public comment are not required for this rule of agency organization, procedure, or practice. 5 U.S.C. 553(b)(A).

Regulatory Flexibility Act

Because notice and comment are not required under 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are inapplicable. As such, a regulatory flexibility analysis is not required, and none has been prepared.

Paperwork Reduction Act

Notwithstanding any other provision of the law, no person is required to, nor shall any person be subject to penalty for failure to comply with, a collection of information, subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB Control Number.

There are no collections of information involved in this rulemaking.

National Environmental Policy Act

This rule will not significantly affect the quality of the human environment. Therefore, an environmental assessment or Environmental Impact Statement is not required to be prepared under the National Environmental Policy Act of 1969.

List of Subjects in 15 CFR Part 270

Administrative practice and procedure; Buildings and facilities; Disaster assistance; Evidence; Investigations; National Institute of Standards and Technology; Science and technology; Subpoena.

Dated: May 2, 2003.

Karen H. Brown,

Deputy Director.

■ For the reasons set forth in the preamble, Title 15 of the Code of Federal Regulations is amended as follows:

PART 270—NATIONAL CONSTRUCTION SAFETY TEAMS

■ 1. The authority citation for part 270 is revised to read as follows:

Authority: Pub. L. 107–231, 116 Stat. 1471 (15 U.S.C. 7301 *et seq.*).

■ 2. Section 270.310 is amended by revising the introductory text to read as follows:

§ 270.310 Evidence collected by investigation participants who are not NIST employees.

Upon receipt of evidence pursuant to an investigation under the Act, each investigation participant who is not a NIST employee shall:

* * * * *

§ 270.312 [Amended]

■ 3. Section 270.312 is amended by removing the last sentence.

§ 270.314 [Amended]

■ 4. In § 270.314, the reference to ''§ 270.312'' is revised to read ''§ 270.313''.

■ 5. Section 270.315 is amended by revising paragraph (d)(2) to read as follows:

§ 270.315 Subpoenas.

* * * * *

(d) * * *

(2) By certified mail, return receipt requested, or delivery to the last known residence or business address of such person or agent; or

* * *

* * * * *

[FR Doc. 03–11361 Filed 5–6–03; 8:45 am]

BILLING CODE 3510–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 232

[Release Nos. 33–8224; 34–47766; 35–27672; 39–2407; IC–26032]

RIN 3235–AG96

Adoption of Updated EDGAR Filer Manual

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission (the Commission) is adopting revisions to the EDGAR Filer Manual to reflect updates to the EDGAR system based upon recent rulemaking activity related to mandating the electronic filing, and Web site posting by issuers with corporate Web sites, of beneficial ownership reports filed by officers, directors and principal security holders under section 16(a) of the Securities Exchange Act of 1934, generally as required by section 403 of the Sarbanes-Oxley Act of 2002, as well as the fact that EDGAR will no longer accept magnetic tape cartridges as a filing medium. The new release will include a new Online Forms Internet Web site (*https://www.onlineforms.edgarfiling.sec.gov*) that will allow for the online creation and submission of ownership reports Forms 3, 4 and 5; their amendments, Forms 3/A, 4/A and 5/A; and, a minor update to EDGARLink submission template 2 to disallow the filing of the ownership forms due to the online capability. The revisions to the Filer Manual reflect these changes, most significantly, within the addition of a third Volume entitled ''EDGAR Release 8.5 OnlineForms Filer Manual Volume III.'' Volumes I and II of the Filer Manual, EDGARLink and the N–SAR Supplement respectively, have been modified, mainly, to reference the new Online Forms Web site and the removal of magnetic tape cartridges as a filing medium. Support for filing via magnetic tape cartridges is being removed due to lack of use by filers. This feature was last used officially by a filer, for a live filing, in 2001, and only by a few filers that whole year. The updated manual will be incorporated by reference into the Code of Federal Regulations.

EFFECTIVE DATE: May 7, 2003. The incorporation by reference of the EDGAR Filer Manual is approved by the Director of the Federal Register as of May 7, 2003.

FOR FURTHER INFORMATION CONTACT: In the Office of Information Technology, Rick Heroux at (202) 942–8800; for questions concerning Investment Management company filings, Ruth Armfield Sanders, Senior Special Counsel, or Shaswat K. Das, Senior Counsel, Division of Investment Management, at (202) 942–0978; and for questions concerning Corporation Finance company filings, Herbert Scholl, Office Chief, EDGAR and Information Analysis, Division of Corporation Finance, at (202) 942–2940.

SUPPLEMENTARY INFORMATION: Today we are adopting an updated EDGAR Filer Manual (Filer Manual). The Filer Manual describes the technical formatting requirements for the preparation and submission of electronic filings through the Electronic Data Gathering, Analysis, and Retrieval (EDGAR) system.[1] It also describes the requirements for filing using modernized EDGARLink.[2]

The Filer Manual contains all the technical specifications for filers to submit filings using the EDGAR system. Filers must comply with the applicable provisions of the Filer Manual in order to assure the timely acceptance and processing of filings made in electronic

[1] We originally adopted the Filer Manual on April 1, 1993, with an effective date of April 26, 1993. Release No. 33–6986 (Apr. 1, 1993) [58 FR 18638]. We implemented the most recent update to the Filer Manual on September 17, 2001. See Release No. 33–8007 (September 24, 2001) [66 FR 49829].

[2] This is the filer assistance software we provide filers filing on the EDGAR system.

format.[3] Filers should consult the Filer Manual in conjunction with our rules governing mandated electronic filing when preparing documents for electronic submission.[4]

Based upon recent rulemaking activity related to mandating the electronic filing, and Web site posting by issuers with corporate Web sites, of beneficial ownership reports filed by officers, directors and principal security holders under section 16(a) of the Securities Exchange Act of 1934, generally as required by section 403 of the Sarbanes-Oxley Act of 2002, EDGAR Release 8.5 will be implemented on May 5, 2003. This release includes a new Online Forms Internet Web site (*https://www.onlineforms.edgarfiling.sec.gov*) that will support the online creation and submission of ownership reports Forms 3, 4 and 5; their amendments, Forms 3/A, 4/A and 5/A; and, a minor update to EDGARLink submission template 2 to disallow the filing of the ownership forms due to the online capability. The release also includes a patch to the EDGARLink software, which provides improved precision of the fee and interest calculations. The patch is only necessary for those filers that will assemble fee-bearing filings. EDGAR 8.5 supports backward compatibility with the current version of the EDGARLink templates. Notice of the update has previously been provided on the EDGAR filing Web site and on the Commission's public Web site. The discrete updates are reflected on the filing Web site and in the updated Filer Manual Volumes.

The new Web site has been designed to make it easier for individuals to satisfy the electronic filing obligations that will apply to them when electronic submission of these Forms is mandated later this year. Another benefit of the new release is that, in addition to the ownership reports Forms 3, 3/A, 4, 4/A, 5 and 5/A, the new EDGAR Online Forms Web site can be used for the online filing of other forms, that may be included in future SEC rulemaking activity, when they become technically available.

Along with adoption of the Filer Manual, we are amending Rule 301 of Regulation S–T to provide for the incorporation by reference into the Code of Federal Regulations of today's revisions. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

You may obtain paper copies of the updated Filer Manual at the following address: Public Reference Room, U.S. Securities and Exchange Commission, 450 Fifth Street, NW., Washington DC 20549–0102. We will post electronic format copies on the Commission's Web site; the address for the Filer Manual is <*http://www.sec.gov/info/edgar.shtml*>. You may also obtain copies from Thomson Financial Inc, the paper and microfiche contractor for the Commission, at (800) 638–8241.

Since the Filer Manual relates solely to agency procedures or practice, publication for notice and comment is not required under the Administrative Procedure Act (APA).[5] It follows that the requirements of the Regulatory Flexibility Act [6] do not apply.

The effective date for the updated Filer Manual and the rule amendments is May 7, 2003. In accordance with the APA,[7] we find that there is good cause to establish an effective date less than 30 days after publication of these rules. The EDGAR system upgrade to Release 8.5 is scheduled to occur on May 3, 2003, becoming available on May 5, 2003. The Commission believes that it is necessary to coordinate the effectiveness of the updated Filer Manual with the scheduled system upgrade.

Statutory Basis

We are adopting the amendments to Regulation S–T under sections 6, 7, 8, 10, and 19(a) of the Securities Act,[8] sections 3, 12, 13, 14, 15, 23, and 35A of the Securities Exchange Act of 1934,[9] section 20 of the Public Utility Holding Company Act of 1935,[10] section 319 of the Trust Indenture Act of 1939,[11] and sections 8, 30, 31, and 38 of the Investment Company Act of 1940.[12]

List of Subjects in 17 CFR Part 232

Incorporation by reference, Reporting and recordkeeping requirements, Securities.

Text of the Amendment

■ In accordance with the foregoing, Title 17, Chapter II of the Code of Federal Regulations is amended as follows:

PART 232—REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

■ 1. The authority citation for Part 232 continues to read as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s(a), 77sss(a), 78c(b), 78*l*, 78m, 78n, 78o(d), 78w(a), 78*ll*(d), 79t(a), 80a–8, 80a–29, 80a–30 and 80a–37.

■ 2. Section 232.301 is revised to read as follows:

§ 232.301 EDGAR Filer Manual.

Filers must prepare electronic filings in the manner prescribed by the EDGAR Filer Manual, promulgated by the Commission, which sets out the technical formatting requirements for electronic submissions. The requirements for filers using modernized EDGARLink are set forth in the EDGAR Release 8.5 EDGARLink Filer Manual Volume I, dated April 2003. Additional provisions applicable to Form N–SAR filers and Online Forms filers are set forth in the EDGAR Release 8.5 Filer Manual Volume II N–SAR Supplement, dated April 2003, and EDGAR Release 8.5 Online Forms Filer Manual Volume III, dated April 2003. All of these provisions have been incorporated by reference into the Code of Federal Regulations, which action was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You must comply with these requirements in order for documents to be timely received and accepted. You can obtain paper copies of the EDGAR Filer Manual from the following address: Public Reference Room, U.S. Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0102 or by calling Thomson Financial Inc at (800) 638–8241. Electronic format copies are available on the Commission's Web site. The address for the Filer Manual is <*http://www.sec.gov/info/edgar.shtml*>. You can also photocopy the document at the

---

[3] *See* Rule 301 of Regulation S–T (17 CFR 232.301).

[4] *See* Release Nos. 33–6977 (Feb. 23, 1993) [58 FR 14628], IC–19284 (Feb. 23, 1993) [58 FR 14848], 35–25746 (Feb. 23, 1993) [58 FR 14999], and 33–6980 (Feb. 23, 1993) [58 FR 15009] in which we comprehensively discuss the rules we adopted to govern mandated electronic filing. *See also* Release No. 33–7122 (Dec. 19, 1994) [59 FR 67752], in which we made the EDGAR rules final and applicable to all domestic registrants; Release No. 33–7427 (July 1, 1997) [62 FR 36450], in which we adopted minor amendments to the EDGAR rules; Release No. 33–7472 (Oct. 24, 1997) [62 FR 58647], in which we announced that, as of January 1, 1998, we would not accept in paper filings that we require filers to submit electronically; Release No. 34–40934 (Jan. 12, 1999) [64 FR 2843], in which we made mandatory the electronic filing of Form 13F; Release No. 33–7684 (May 17, 1999) [64 FR 27888], in which we adopted amendments to implement the first stage of EDGAR modernization; Release No. 33–7855 (April 24, 2000) [65 FR 24788], in which we implemented EDGAR Release 7.0; Release No. 33–7999 (August 7, 2001) [66 FR 42941], in which we implemented EDGAR Release 7.5; Release No. 33–8007 (September 24, 2001) [66 FR 42829], in which we implemented EDGAR Release 8.0.

[5] 5 U.S.C. 553(b).

[6] 5 U.S.C. 601–612.

[7] 5 U.S.C. 553(d)(3).

[8] 15 U.S.C. 77f, 77g, 77h, 77j, and 77s(a).

[9] 15 U.S.C. 78c, 78*l*, 78m, 78n, 78o, 78w, and 78*ll*.

[10] 15 U.S.C. 79t.

[11] 15 U.S.C. 77sss.

[12] 15 U.S.C. 80a–8, 80a–29, 80a–30, and 80a–37.

Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.

By the Commission.

Dated: April 30, 2003.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–11208 Filed 5–6–03; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310 and 358

[Docket No. 02N–0359]

RIN 0910–AA01

Ingrown Toenail Relief Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule establishing conditions under which over-the-counter (OTC) ingrown toenail relief drug products containing sodium sulfide 1 percent in a gel vehicle are generally recognized as safe and effective and not misbranded. This rule also amends the regulation that lists nonmonograph active ingredients in OTC drug products for ingrown toenail relief by removing sodium sulfide from that list. This final rule is part of FDA's ongoing review of OTC drug products.

DATES: This rule is effective June 6, 2003.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2307.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 9, 1993 (58 FR 47602), FDA published a final rule establishing that any ingrown toenail relief drug product for OTC human use is not generally recognized as safe and effective and is misbranded. (See 21 CFR 310.538.) In that final rule, sodium sulfide 1 percent was considered effective but not safe for the temporary relief of pain associated with ingrown toenails because of its potential for causing adverse reactions, particularly burning sensations and skin irritation.

In the **Federal Register** of October 4, 2002 (67 FR 62218), after reviewing new data that had been submitted, FDA proposed to establish conditions under which OTC ingrown toenail relief drug products containing sodium sulfide 1 percent in a gel vehicle are generally recognized as safe and effective and not misbranded. The product is used with a retainer ring to keep the product at the area of application. The agency also proposed to amend the regulation (21 CFR 310.538) that lists nonmonograph active ingredients in OTC drug products for ingrown toenail relief by removing sodium sulfide from that list.

II. Comments Received in Response to the Proposal

In response to the proposal, the agency received two comments, which are on public display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. One comment, from a drug manufacturer, supported the agency's proposals and requested that the agency's review of the comments and publication of the final rule be completed as expeditiously as possible. The second comment, from a consumer, stated that the use of the product with a ''restraining'' ring as indicated should have a ''green light.'' The comment added that there are many people who experience the pain of an ingrown toenail, and that these products will help.

III. The Agency's Final Conclusions

The agency concludes that the data support OTC drug monograph status for 1 percent sodium sulfide in a gel vehicle applied topically for the relief of discomfort (pain) of ingrown toenail. The product is used with a retainer ring to keep the product at the area of application. Accordingly, the agency is proposing a new monograph in part 358, subpart D (21 CFR part 358, subpart D) for ingrown toenail relief drug products that includes 1 percent sodium sulfide gel. The agency is also amending § 310.538 to state that it no longer applies to sodium sulfide.

Mandating warnings in an OTC drug monograph does not require a finding that any or all of the OTC drug products covered by the monograph actually caused an adverse event, and FDA does not so find. Nor does FDA's requirement of warnings repudiate the prior OTC drug monographs and monograph rulemakings under which the affected drug products have been lawfully marketed. Rather, as a consumer protection agency, FDA has determined that warnings are necessary to ensure that these OTC drug products continue to be safe and effective for their labeled indications under ordinary conditions of use as those terms are defined in the Federal Food, Drug, and Cosmetic Act. This judgment balances the benefits of these drug products against their potential risks (see 21 CFR 330.10(a)).

FDA's decision to act in this instance need not meet the standard of proof required to prevail in a private tort action (*Glastetter* v. *Novartis Pharmaceuticals, Corp.*, 252 F.3d 986, 991 (8th Cir. 2001)). To mandate warnings, or take similar regulatory action, FDA need not show, nor do we allege, actual causation. For an expanded discussion of case law supporting FDA's authority to require such warnings, see Labeling of Diphenhydramine-Containing Drug Products for Over-the-Counter Human Use, Final Rule (67 FR 72555, December 6, 2002).

IV. Analysis of Impacts

FDA has examined the impacts of this final 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 believes that this final rule is consistent with the principles set out in Executive Order 12866 and in these two statutes. FDA has determined that the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order. As explained later in this section, FDA concludes that the final rule will not have a significant economic impact on a substantial number of small entities. The Unfunded Mandates Reform Act