

entities. Reclassification of this device when it is used for the topical approximation of skin, from class III to class II, will relieve manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act (21 U.S.C. 360e). Because reclassification will reduce regulatory costs with respect to this device, the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$127 million, using the most current (2006) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this rule to result in any 1-year expenditure that would meet or exceed this amount.

XII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the 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 has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XIII. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 is not required. Elsewhere in this issue of the **Federal Register**, FDA is issuing a notice announcing the guidance for the final rule. This guidance, "Class II Special Controls Guidance Document: Tissue Adhesive for the Topical Approximation of Skin," references previously approved collections of information found in FDA regulations.

XIV. References

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Regulatory & Clinical Research Institute, Inc. (RCRI), reclassification petition, Docket No. 2006P-0071, Minneapolis, MN, February 9, 2006.
2. Regulatory & Clinical Research Institute, Inc., reclassification petition, Docket No. 2006P-0071, Minneapolis, MN, May 15, 2006.
3. Regulatory & Clinical Research Institute, Inc., reclassification petition, Docket No. 2006P-0071, Minneapolis, MN, July 18, 2006.
4. General and Plastic Surgery Devices Panel, transcript, pp. 199 to 207, August 25, 2006.

List of Subjects in 21 CFR Part 878

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Section 878.4010 is added to subpart E to read as follows:

§ 878.4010 Tissue adhesive.

(a) *Tissue adhesive for the topical approximation of skin*—(1) *Identification.* A tissue adhesive for the topical approximation of skin is a device intended for topical closure of surgical incisions, including laparoscopic incisions, and simple traumatic lacerations that have easily approximated skin edges. Tissue adhesives for the topical approximation of skin may be used in conjunction with, but not in place of, deep dermal stitches.

(2) *Classification.* Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance Document: "Tissue Adhesive for the Topical Approximation of Skin." See § 878.1(e) of this chapter for the availability of this guidance document.

(b) *Tissue adhesive for non-topical use*—(1) *Identification.* A tissue adhesive for non-topical use, including adhesives intended for use in the embolization of brain arteriovenous

malformation or for use in ophthalmic surgery, is a device used for adhesion of internal tissues and vessels.

(2) *Classification.* Class III (premarket approval). As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 878.3 of this chapter.

Dated: May 21, 2008.

Daniel G. Schultz,

Center for Devices and Radiological Health.
[FR Doc. E8-12078 Filed 5-29-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

49 CFR Parts 1114, 1121, 1150, and 1180

[STB Ex Parte No. 575 (Sub-No. 1)]

Disclosure of Rail Interchange Commitments

AGENCY: Surface Transportation Board, Department of Transportation.

ACTION: Final rule.

SUMMARY: The Surface Transportation Board is amending its regulations to require that parties seeking to obtain an individual exemption for, or to invoke a class exemption covering, a transaction involving the sale or lease of a railroad line identify any provision in their agreements that would restrict the ability of the purchaser or tenant railroad to interchange traffic with a rail carrier other than the seller or landlord railroad (interchange commitment). The rules also provide a procedure whereby a shipper or other affected party may obtain access to such provisions. The Board is adopting these regulations to facilitate the case-specific review of challenges involving interchange commitments and to facilitate the Board's monitoring of their usage. The final rule appears below.

DATES: *Effective Date:* This rule is effective on June 29, 2008.

FOR FURTHER INFORMATION CONTACT: Joseph H. Dettmar (202) 245-0395. [Federal Information Relay Service (FIRS) for the hearing impaired: 1-800-877-8339.]

SUPPLEMENTARY INFORMATION:

Additional information and background on the regulations appear in our written decision in *Disclosure of Rail Interchange Commitments*, STB Ex Parte No. 575 (Sub-No. 1), which is being served along with this notice.

Except as noted in this agency's decision adopting the final rules, the

comments received in response to our prior notice give us no reason to modify the regulations as proposed. In our decision, we have addressed arguments that the disclosure of interchange commitments that we are seeking is more extensive than necessary, or not extensive enough, for proper performance of our statutory functions. No party has challenged our burden estimates or proposed a way to further minimize the burden on respondents from collection of the information¹ and still provide the required information.

Board decisions, notices, and filings are available on our Web site at <http://www.stb.dot.gov>.

Pursuant to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, and Office of Management and Budget (OMB) regulations at 5 CFR 1320.11, the Surface Transportation Board has obtained OMB approval for the collection of information adopted here.

This collection of information has been assigned OMB Control No. 2140-0016. Unless renewed, OMB approval expires on January 31, 2011. The display of a currently valid OMB control number for this collection is required by law. Under the PRA and 5 CFR 1320.8, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a currently valid OMB control number.

Pursuant to 5 U.S.C. 605(b), we reaffirm our finding in the **Federal Register** on November 2, 2007, that our action in this proceeding will not have a significant impact on a substantial number of small entities.

List of Subjects

49 CFR Part 1114

Administrative practice and procedure.

49 CFR Parts 1121 and 1150

Administrative practice and procedure, Railroads.

49 CFR Part 1180

Administrative practice and procedure, Railroads, Reporting and recordkeeping requirements.

Authority: 49 U.S.C. 721, 5 U.S.C. 553.

Decided: May 21, 2008.

By the Board, Chairman Nottingham, Vice Chairman Mulvey, and Commissioner Buttrey.

Anne K. Quinlan,

Acting Secretary.

■ For the reasons set forth in the preamble, parts 1114, 1121, 1150, and 1180, of title 49, chapter X, of the Code of Federal Regulations are amended as follows:

PART 1114—EVIDENCE; DISCOVERY

■ 1. The authority citation for part 1114 continues to read as follows:

Authority: 5 U.S.C. 559; 49 U.S.C. 721.

■ 2. Amend § 1114.30 by adding paragraph (d) to read as follows:

§ 1114.30 Production of documents and records and entry upon land for inspection and other purposes.

* * * * *

(d) *Agreements containing interchange commitments.* In any proceeding involving the reasonableness of provisions related to an existing rail carrier sale or lease agreement that serve to induce a party to the agreement to interchange traffic with another party to the agreement, rather than with a third-party connecting carrier, whether by outright prohibition, per-car penalty, adjustment in the purchase price or rental, positive economic inducement, or other means, a party to the proceeding with a need for the information may obtain a confidential, complete version of the agreement, with the prior approval of the Board. The party seeking such approval must file an appropriate motion containing an explanation of the party's need for the information and a draft protective order and undertaking(s) that will ensure the agreement is kept confidential. The motion seeking approval may be filed at any time after the initial complaint or petition, including before the answer to the complaint or petition is due. A reply to such a motion must be filed within 5 days thereafter. The motion will be considered by the Board in an expedited manner.

PART 1121—RAIL EXEMPTION PROCEDURES

■ 3. The authority citation for part 1121 continues to read as follows:

Authority: 49 U.S.C. 10502 and 10704.

■ 4. Amend § 1121.3 by adding paragraph (d) to read as follows:

§ 1121.3 Content.

* * * * *

(d) *Transactions imposing interchange commitments.* (1) If a

proposed acquisition or operation of a rail line involves a provision or agreement that may limit future interchange with a third-party connecting carrier, whether by outright prohibition, per-car penalty, adjustment in the purchase price or rental, positive economic inducement, or other means ("interchange commitment"), the following additional information must be provided:

(i) The existence of that provision or agreement and identification of the affected interchange points; and

(ii) A confidential, complete version of the document(s) containing or addressing that provision or agreement, which may be filed with the Board under 49 CFR 1104.14(a) and will be kept confidential without need for the filing of an accompanying motion for a protective order under 49 CFR 1104.14(b).

(2) To obtain information about an interchange commitment for use in a proceeding before the Board, a shipper or other affected party may be granted access to the confidential documents filed pursuant to paragraph (d)(1) of this section by filing, and serving upon the petitioner, a "Motion for Access to Confidential Documents," containing:

(i) An explanation of the party's need for the information; and

(ii) An appropriate draft protective order and confidentiality undertaking(s) that will ensure that the documents are kept confidential.

(3) Deadlines.

(i) Replies to a Motion for Access are due within 5 days after the motion is filed.

(ii) The Board will rule on a Motion for Access within 30 days after the motion is filed.

(iii) Parties must produce the relevant documents within 5 days of receipt of a Board approved, signed confidentiality agreement.

PART 1150—CERTIFICATE TO CONSTRUCT, ACQUIRE, OR OPERATE RAILROAD LINES

■ 5. The authority citation for part 1150 continues to read as follows:

Authority: 49 U.S.C. 721(a), 10502, 10901, and 10902.

■ 6. Amend § 1150.33 by adding paragraph (h) to read as follows:

§ 1150.33 Information to be contained in notice—transactions that involve creation of Class III carriers.

* * * * *

(h) *Transactions imposing interchange commitments.* (1) If a proposed acquisition or operation of a rail line or change of operators involves

¹ In the discussion pertaining to small entities in our notice published on November 2, 2007, we explained why the burden of collection would be minimal. No party has disputed our explanation.

a provision or agreement that may limit future interchange with a third-party connecting carrier, whether by outright prohibition, per-car penalty, adjustment in the purchase price or rental, positive economic inducement, or other means ("interchange commitment"), the following additional information must be provided:

(i) The existence of that provision or agreement and identification of the affected interchange points; and

(ii) A confidential, complete version of the document(s) containing or addressing that provision or agreement, which may be filed with the Board under 49 CFR 1104.14(a) and will be kept confidential without need for the filing of an accompanying motion for a protective order under 49 CFR 1104.14(b).

(2) To obtain information about an interchange commitment for use in a proceeding before the Board, a shipper or other affected party may be granted access to the confidential documents filed pursuant to paragraph (h)(1) of this section by filing, and serving upon the petitioner, a "Motion for Access to Confidential Documents," containing:

(i) An explanation of the party's need for the information; and

(ii) An appropriate draft protective order and confidentiality undertaking(s) that will ensure that the documents are kept confidential.

(3) Deadlines.

(i) Replies to a Motion for Access are due within 5 days after the motion is filed.

(ii) The Board will rule on a Motion for Access within 30 days after the motion is filed.

(iii) Parties must produce the relevant documents within 5 days of receipt of a Board approved, signed confidentiality agreement.

■ 7. Amend § 1150.43 by adding paragraph (h) to read as follows:

§ 1150.43 Information to be contained in notice for small line acquisitions.

* * * * *

(h) *Transactions imposing interchange commitments.* (1) If a proposed acquisition or operation of a rail line or change of operators involves a provision or agreement that may limit

future interchange with a third-party connecting carrier, whether by outright prohibition, per-car penalty, adjustment in the purchase price or rental, positive economic inducement, or other means ("interchange commitment"), the following additional information must be provided:

(i) The existence of that provision or agreement and identification of the affected interchange points; and

(ii) A confidential, complete version of the document(s) containing or addressing that provision or agreement, which may be filed with the Board under 49 CFR 1104.14(a) and will be kept confidential without need for the filing of an accompanying motion for a protective order under 49 CFR 1104.14(b).

(2) To obtain information about an interchange commitment for use in a proceeding before the Board, a shipper or other affected party may be granted access to the confidential documents filed pursuant to paragraph (h)(1) of this section by filing, and serving upon the petitioner, a "Motion for Access to Confidential Documents," containing:

(i) An explanation of the party's need for the information; and

(ii) An appropriate draft protective order and confidentiality undertaking(s) that will ensure that the documents are kept confidential.

(3) Deadlines.

(i) Replies to a Motion for Access are due within 5 days after the motion is filed.

(ii) The Board will rule on a Motion for Access within 30 days after the motion is filed.

(iii) Parties must produce the relevant documents within 5 days of receipt of a Board approved, signed confidentiality agreement.

PART 1180—RAILROAD ACQUISITION, CONTROL, MERGER, CONSOLIDATION PROJECT, TRACKAGE RIGHTS, AND LEASE PROCEDURES

■ 8. The authority citation for part 1180 continues to read as follows:

Authority: 5 U.S.C. 553 and 559; 11 U.S.C. 1172; 49 U.S.C. 721, 10502, 11323–11325.

■ 9. Amend § 1180.4 by adding paragraph (g)(4) to read as follows:

§ 1180.4 Procedures.

(g) *Notice of exemption.* * * *

(4) *Transactions imposing interchange commitments.* (i) If a proposed acquisition or operation of a rail line involves a provision or agreement that may limit future interchange with a third-party connecting carrier, whether by outright prohibition, per-car penalty, adjustment in the purchase price or rental, positive economic inducement, or other means ("interchange commitment"), the following additional information must be provided:

(A) The existence of that provision or agreement and identification of the affected interchange points; and

(B) A confidential, complete version of the document(s) containing or addressing that provision or agreement, which may be filed with the Board under 49 CFR 1104.14(a) and will be kept confidential without need for the filing of an accompanying motion for a protective order under 49 CFR 1104.14(b).

(ii) To obtain information about an interchange commitment for use in a proceeding before the Board, a shipper or other affected party may be granted access to the confidential documents filed pursuant to § 1180.4(g)(4)(i) of this section by filing, and serving upon the petitioner, a "Motion for Access to Confidential Documents," containing:

(A) An explanation of the party's need for the information; and

(B) An appropriate draft protective order and confidentiality undertaking(s) that will ensure that the documents are kept confidential.

(iii) Deadlines.

(A) Replies to a Motion for Access are due within 5 days after the motion is filed.

(B) The Board will rule on a Motion for Access within 30 days after the motion is filed.

(C) Parties must produce the relevant documents within 5 days of receipt of a Board approved, signed confidentiality agreement.

[FR Doc. E8–11952 Filed 5–29–08; 8:45 am]

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