Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

■ 4. Section 347.20 is amended by redesignating paragraphs (b), (c), and (d) as paragraphs (c), (d), and (e), respectively, and by adding new paragraph (b) to read as follows:

§ 347.20 Permitted combinations of active ingredients.

* * * * *

(b) *Combination of ingredients to prepare an aluminum acetate solution.* Aluminum sulfate tetradecahydrate may be combined with calcium acetate monohydrate in powder or tablet form to provide a 0.13 to 0.5 percent aluminum acetate solution when the powder or tablet is dissolved in the volume of water specified in ''Directions.''

* * * * *

■ 5. Section 347.52 is amended by revising paragraph (a) and (b)(1) paragraph heading, and by revising paragraphs (c) and (d)(1), and by adding new paragraph (d)(4) to read as follows:

§ 347.52 Labeling of astringent drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an ''astringent.'' *For products containing the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § 347.20(b)*, under the ''Purpose'' heading identified in § 201.66(c)(3) of this chapter, the labeling of each active ingredient in the product states ''Astringent*'', which is followed by the statements ''* When combined together in water, these ingredients form the active ingredient aluminum acetate. See [the following in bold italic type] Directions.''

(b) *Indications.* * * *

(1) *For products containing aluminum acetate identified in § 347.12(a) or the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § 347.20(b).* * * *

* * * * *

(c) *Warnings.* The labeling of the product contains the following warnings under the heading ''Warnings'':

(1) *For all products*—(i) The labeling states ''For external use only''.

(ii) The labeling states ''When using this product [bullet] avoid contact with eyes. If contact occurs, rinse thoroughly with water.''

(2) *For products containing aluminum acetate identified in § 347.12(a), witch hazel identified in § 347.12(c), or the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § 347.20(b).* The labeling states ''Stop use and ask a doctor if [bullet] condition worsens or symptoms last more than 7 days''.

(3) *For products containing aluminum acetate identified in § 347.12(a) or the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § 347.20(b) when labeled for use as a compress or wet dressing.* The labeling states ''When using this product [bullet] do not cover compress or wet dressing with plastic to prevent evaporation''.

(4) *For products containing aluminum acetate identified in § 347.12(a) or the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § 347.20(b) when labeled for use as a soak, compress, or wet dressing.* The labeling states ''When using this product [bullet] in some skin conditions, soaking too long may overdry''.

(d) *Directions.* * * *

(1) *For products containing aluminum acetate identified in § 347.12(a) or the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § 347.20(b)*—(i) *For products used as a soak.* ''For use as a soak: [preceding words in bold type] [bullet] soak affected area for 15 to 30 minutes as needed, or as directed by a doctor [bullet] repeat 3 times a day or as directed by a doctor [bullet] discard solution after each use'' .

(ii) *For products used as a compress or wet dressing.* ''For use as a compress or wet dressing: [preceding words in bold type] [bullet] soak a clean, soft cloth in the solution [bullet] apply cloth loosely to affected area for 15 to 30 minutes [bullet] repeat as needed or as directed by a doctor [bullet] discard solution after each use''.

* * * * *

(4) *For products containing the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § 347.20(b)*—(i) *For powder dosage form.* The labeling states ''[bullet] dissolve 1 to 3 packets in [insert volume] of cool or warm water [bullet] stir until fully dissolved; do not strain or filter. The resulting mixture contains [insert percent] (1 packet), [insert percent] (2 packets), or [insert percent] (3 packets) aluminum acetate and is ready for use.'' These statements shall be the first statements under the heading ''Directions''.

(ii) *For tablet dosage form.* The labeling states ''[bullet] dissolve 1 to 3 tablets in [insert volume] of cool or warm water [bullet] stir until fully dissolved; do not strain or filter. The resulting mixture contains [insert percent] (1 tablet), [insert percent] (2 tablets), or [insert percent] (3 tablets) aluminum acetate and is ready for use.'' These statements shall be the first statements under the heading ''Directions''.

* * * * *

Dated: February 23, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–4746 Filed 3–5–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. FDA–2009–N–0099]

New Drug Applications and Abbreviated New Drug Applications; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its new drug application (NDA) and abbreviated new drug application (ANDA) regulations to update agency contacts for patent information and patent notifications and to correct an inaccurate cross-reference. This action is being taken to ensure accuracy and clarity in the agency's regulations.

DATES: This rule is effective March 6, 2009.

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 51, rm. 6308, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3506.

SUPPLEMENTARY INFORMATION: FDA is amending its NDA and ANDA regulations in part 314 (21 CFR part 314) to update agency contacts for information and notifications pertaining to patents and to correct an inaccurate reference. To accommodate the ongoing relocation of FDA offices, users are directed to FDA's Web site to obtain the current address of the Office of Generic Drugs.

In §§ 314.52(a)(2) and 314.95(a)(2), FDA is updating the agency contact for obtaining the name and address of the NDA holder or designee for purposes of providing notice of a patent certification submitted under section 505(b)(2)(A)(iv)

or 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(b)(2)(A)(iv) or 355(j)(2)(A)(vii)(IV)). The Division of Drug Information Resources no longer exists. The agency contact for this information is now the Orange Book Staff, Office of Generic Drugs.

In § 314.53(f), FDA is updating the agency unit to which notifications of requests for correction of patent information should be directed. The Drug Information Services Branch no longer exists. These notifications should now be sent to the Office of Generic Drugs Document Room, attention the Orange Book Staff.

In § 314.107(e), FDA is updating the listing of agency units to which a 505(b)(2) applicant must send notification of entry of an order or judgment in a court action. Instead of the appropriate division in the Office of Drug Evaluation I and Office of Drug Evaluation II, these notifications should now be sent to the appropriate division in the Office of New Drugs.

In § 314.107(f)(2)(iv), FDA is updating the agency recipient of a 505(b)(2) applicant's required notification that a legal action has been filed within 45 days of receipt of a notice of paragraph IV certification (submitted under section 505(b)(2)(A)(iv) of the act) from the appropriate division in the Center for Drug Evaluation and Research to the appropriate division in the Office of New Drugs.

In § 314.125(b)(16), FDA is correcting a cross-reference to the agency's regulations on institutional review boards (21 CFR part 56) by replacing ''part 58'' with ''part 56.''

Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because the amendments to the regulations provide only technical changes to correct an inaccurate citation and to update agency contacts, and are nonsubstantive.

List of Subjects in 21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 314 is amended as follows:

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 1. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 356a, 356b, 356c, 371, 374, 379e.

§ 314.52 [Amended]

■ 2. Section 314.52 is amended in paragraph (a)(2) by removing ''Division of Drug Information Resources (HFD–80), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857'' and by adding in its place ''Orange Book Staff, Office of Generic Drugs, at the address identified on FDA's Web site (*http://www.fda.gov/cder/ogd*)''.

§ 314.53 [Amended]

■ 3. Section 314.53 is amended in paragraph (f) by removing ''Drug Information Services Branch (HFD–84), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857'' and by adding in its place ''Office of Generic Drugs, OGD Document Room, Attention: Orange Book Staff, at the address identified on FDA's Web site (*http://www.fda.gov/cder/ogd*)''.

§ 314.95 [Amended]

■ 4. Section 314.95 is amended in paragraph (a)(2) by removing ''Division of Drug Information Resources (HFD–80), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857'' and by adding in its place ''Orange Book Staff, Office of Generic Drugs, at the address identified on FDA's Web site (*http://www.fda.gov/cder/ogd*)''.

§ 314.107 [Amended]

■ 5. Section 314.107 is amended in paragraph (e) by removing ''Office of Drug Evaluation I (HFD–100) or Office of Drug Evaluation II (HFD–500), whichever is applicable,'' and by adding in its place ''Office of New Drugs'' and in paragraph (f)(2)(iv) by removing ''Center for Drug Evaluation and Research'' and by adding in its place ''Office of New Drugs''.

§ 314.125 [Amended]

■ 6. Section 314.125 is amended in paragraph (b)(16) by removing ''part 58'' and by adding in its place ''part 56''.

Dated: February 27, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy.

[FR Doc. E9–4813 Filed 3–5–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 529

[Docket No. FDA–2009–N–0665]

New Animal Drugs; Change of Sponsor; Methoxyflurane

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) from Schering-Plough Animal Health, Inc., to Medical Developments International, Ltd.

DATES: This rule is effective March 6, 2009.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8307, e-mail: *david.newkirk@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 556 Morris Ave., Summit, NJ 07901, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 14–485 for ANAFANE (methoxyflurane) Volatile Liquid for Inhalation Anesthesia to Medical Developments International, Ltd., P.O. Box 21, Sandown Village, 3171 VIC Australia.

Medical Developments International, Ltd., is not currently listed in the animal drug regulations as a sponsor of an approved application. In addition, FDA has noticed that this new animal drug has not been previously codified in 21 CFR part 529. Accordingly, the regulations are amended in 21 CFR 510.600(c) to add entries for Medical Developments International, Ltd., and in 21 CFR part 529 to add this new animal drug.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.