COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 170

RIN 3038–AE09

Membership in a Registered Futures Association

Correction

In proposed rule document 13–26790 beginning on page 67078 in the issue of Friday, November 8, 2013, make the following correction:

On page 67078, in the third column, under **DATES**, in the last line ''January 17, 2014'' should read ''January 7, 2014''.

[FR Doc. C1–2013–26790 Filed 11–12–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 601

[Docket No. FDA–2013–N–0500]

RIN 0910–AG94

Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is proposing to amend its regulations to revise and clarify procedures for application holders of an approved drug or biological product to change the product labeling to reflect certain types of newly acquired information in advance of FDA's review of the change. The proposed rule would create parity among application holders with respect to such labeling changes by permitting holders of abbreviated new drug applications (ANDAs) to distribute revised product labeling that differs in certain respects, on a temporary basis, from the labeling of its reference listed drug (RLD) upon submission to FDA of a ''changes being effected'' (CBE–0) supplement. The proposed rule describes the process by which information regarding a CBE–0 labeling supplement submitted by a new drug application (NDA) holder, an ANDA holder, or a biologics license application (BLA) holder would be made publicly available during FDA's review of the labeling change and clarifies requirements for all ANDA holders to submit conforming labeling revisions after FDA has taken an action on the NDA or ANDA holder's CBE–0 labeling supplement. The proposed rule also would amend the regulations to allow submission of a CBE–0 labeling supplement for certain changes to the ''Highlights of Prescribing Information'' for drug products with labeling in the ''Physician Labeling Rule'' (PLR) format.

DATES: Submit either electronic or written comments on the proposed rule by January 13, 2014. See section VII for the proposed effective date of a final rule based on this proposed rule. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (the PRA) by December 13, 2013, (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA–2013–N–0500 and/or Regulatory Information Number (RIN) 0910–AG94, by any of the following methods, except that comments on information collection issues under the PRA must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2013–N–0500 and RIN 0910–AG94 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Janice L. Weiner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6304, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION:

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Executive Summary

Purpose of the Regulatory Action

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 et seq.) and the Public Health Service Act (the PHS Act) (42 U.S.C. 201 et seq.) provide FDA with authority over the labeling for drugs and biological products, and authorize the Agency to enact regulations to facilitate FDA's review and approval of applications regarding the labeling for those products. FDA is proposing to amend its regulations to revise and clarify procedures for application holders to change the labeling of an approved drug or biological product to reflect certain types of newly acquired information in advance of FDA's review of the change through a CBE–0 supplement. The proposed rule would create parity among application holders with respect to these safety-related labeling changes by permitting ANDA holders to distribute revised generic drug labeling that differs in certain respects, on a temporary basis, from the RLD labeling upon submission to FDA of a CBE–0 supplement.