

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. FDA-2008-N-0341]

Applications for Food and Drug Administration Approval to Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) published in the **Federal Register** of September 29, 2008 (73 FR 56487), a direct final rule amending its regulations to require that the holder of a new drug application (NDA) submit certain information regarding authorized generic drugs in an annual report to a central office in the agency. The comment period closed December 15, 2008. FDA is withdrawing the direct final rule because the agency received significant adverse comment.

DATES: The direct final rule published at 73 FR 56487 on September 29, 2008, is withdrawn as of *[insert date of publication in the Federal Register]*.

FOR FURTHER INFORMATION CONTACT: Michelle D.D. Bernstein, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6362, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: FDA published a direct final rule on September 29, 2008 (73 FR 56487), that was intended to amend its regulations to require

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that the holder of an NDA submit certain information regarding authorized generic drugs in an annual report to a central office in the agency. In response to the direct final rule, the agency received significant adverse comments about the proposed revisions to the rule.

Under FDA's direct final rules procedures, the receipt of any significant adverse comment will result in the withdrawal of the direct final rule. Thus, this direct final rule is being withdrawn, effective immediately. Comments received by the agency regarding the withdrawn rule will be considered in developing a final rule using the usual Administrative Procedure Act notice-and-comment procedures.

Authority: Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, the direct final rule published on September 29, 2008 (73 FR 56487), is withdrawn.

Dated: February 5, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. 09-????? Filed ??-??-09; 8:45 am]

BILLING CODE 4160-01-S
