Guidance for Industry

Accelerated Approval Products — Submission of Promotional Materials

DRAFT GUIDANCE

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Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions on the content of the draft document contact (CDER) Tracy L. Acker, 301-827-2831 or (CBER) Toni M. Stifano, 301- 827-3028.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
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Division of Communications Management
Drug Information Branch, HFD-210
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Food and Drug Administration
5600 Fishers Lane, Rockville, MD 20857
(Phone 301-827-4573)
Internet: http://www.fda.gov/cder/guidance/index.htm.

or

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U.S. Department of Health and Human Services
Food and Drug Administration
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GUIDANCE FOR INDUSTRY[1]

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I. INTRODUCTION

This guidance is intended to describe procedures that sponsors of human prescription drug and biological products can use to submit promotional materials to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) under 21 CFR 314.550 and 601.45 for products approved under the accelerated approval regulations[2].

In the context of this draft guidance, the term *promotional materials* includes promotional labeling and advertisements. Examples of labeling include, but are not limited to, brochures, booklets, detailing pieces, bulletins, calendars, motion pictures, and slides (21 CFR 202.1(l)(2)). Advertisements include, but are not limited to, materials published in journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communications systems (§ 202.1(l)(1)).

II. BACKGROUND

In the *Federal Register* of December 11, 1992 (57 FR 58942), FDA published final regulations under which the Agency would accelerate the approval of certain new drugs and biological products for serious or life-threatening illnesses. The accelerated approval regulations require that, unless otherwise informed by the Agency, applicants submit to FDA copies of all promotional materials, including promotional labeling and advertisements, intended for

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[1] This guidance has been prepared by the Division of Drug Marketing, Advertising, and Communications in the Center for Drug Evaluation and Research (CDER) in consultation with the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration. This guidance document represents the Agency's current thinking on the process for submitting promotional materials for accelerated approval products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

[2] Sponsors whose drug or biological product is in a fast track program that is eligible for approval under section 506(b) of the Federal Food, Drug, and Cosmetic Act are also subject to 314.550 and 601.45 and can use these procedures.

dissemination or publication within the first 120 days following marketing approval during the ***preapproval review period*** (see 21 CFR 314.550 and 601.45). The regulations require further that promotional materials intended for dissemination any time after the 120-day postapproval period be submitted at least 30 days prior to the intended date of initial dissemination or publication of those materials, unless otherwise informed by the Agency.

III. COMMUNICATING WITH FDA DURING THE PREAPPROVAL REVIEW PERIOD

To the extent that a sponsor anticipates approval of a product under the accelerated approval provisions, FDA encourages sponsors to begin communication with the appropriate division early in the application review process regarding submission of draft promotional materials for review during the preapproval period. Sponsors should contact CDER, Division of Drug Marketing, Advertising, and Communications (DDMAC) or CBER, Advertising and Promotional Labeling Staff (APLS), Office of Compliance and Biologics Quality. Early communication with DDMAC or APLS should enable the sponsor to understand and comply with the submission requirements prior to product approval or licensing.

IV. PROMOTIONAL MATERIALS INTENDED FOR USE DURING THE 120-DAY POSTMARKETING PERIOD

A. General Requirements for Submission and Review

As previously noted, unless otherwise informed by FDA, applicants must submit to the Agency copies of all promotional materials, including promotional labeling and advertisements, intended for dissemination or publication within 120 days following marketing approval ***prior to*** approval or licensing (21 CFR 314.550 and 601.45). FDA's goal is to provide comments in a timely manner, usually within 15 working days of the day the materials are received by DDMAC or APLS. The Agency expects that materials will ***not*** be disseminated or published until the Agency's objections are resolved. FDA recommends that the applicant plan sufficient time for resolving differences with the Agency concerning the submitted materials prior to dissemination or publication.

In some cases, the sponsor may respond to the Agency's comments on previously submitted materials ***after*** product approval. However, FDA expects that no promotional materials will be disseminated until the Agency's concerns have been resolved.

To the extent that product labeling is not yet final, a sponsor may be unable to provide FDA with final promotional materials prior to product approval. In such instances, the

Agency may be able to comment on many of the important aspects of the promotion based upon draft promotional materials.

B. Submissions During the 120 Day Post Approval Period

FDA expects that all promotional materials intended for use during the 120-day postapproval period will be submitted ***prior*** to product approval. However, FDA recognizes that, on rare occasions, the following circumstances may preclude a sponsor from submitting every promotional item intended for use during the 120 day postapproval period prior to approval:

i. The designation of accelerated approval status occurs late in the preapproval review period or extensive and substantive changes to draft labeling occur so late that completely new promotional materials need to be developed. Under such circumstances, the sponsor should still submit as many materials as possible ***before*** approval.

ii. A sponsor may need to address unforeseen problems or report information in labeling material that is beneficial to fostering the safe and effective use of the product after it has entered the marketplace. For example, a sponsor may have to address an unforeseen problem with product administration or availability, or an unexpectedly high incidence of an adverse event. Sponsors can request that FDA review such additional materials and should provide a rationale for distribution of these materials prior to submission of the actual materials. FDA will respond to such requests in a timely manner and, when appropriate, will provide comments on the materials.

V. PROMOTIONAL MATERIALS INTENDED FOR USE FOLLOWING THE 120-DAY POSTAPPROVAL PERIOD

Promotional materials intended for use following the 120 day postapproval period must be submitted to FDA for review at least 30 days prior to its intended dissemination or publication date, unless otherwise informed by the Agency (21 CFR 314.550 and 601.45). FDA requests that sponsors consider batching these submissions, rather than submitting multiple individual pieces. Batching will facilitate a more expeditious review. Sponsors may submit such materials for review as early as 90 days post approval (30 days prior to intended dissemination or publication). However, such materials should not be used until the Agency's concerns are resolved and until the 120 day postapproval period has expired.

Submissions should be made under cover of a letter to DDMAC or APLS requesting comments on *draft materials*, referencing the materials are being submitted pursuant to 21 CFR 314.550 or 601.45, and should include copies of draft materials and all supporting references necessary for FDA review.

FDA intends to provide the sponsor with comments as soon as possible. If the Agency notifies the sponsor of significant objections to the proposed materials, the Agency expects that these materials will not be disseminated or published until the Agency's concerns have been resolved.

Sponsors often develop promotional materials that are derivative of previously reviewed materials (i.e., materials that present product claims and representations of the same content and context as previously reviewed materials) for use after the 120-day postapproval period. These materials should also be submitted for review prior to use. FDA intends to review and comment on derivative materials in a timely manner, usually within 15 working days of the day the materials are received by FDA.

At the time of initial dissemination or publication, sponsors are required to submit final materials for drug products under cover of FDA Form 2253, pursuant to 21 CFR 314.81(b)(3)(i) and for biological products under cover of FDA Form 2567 or equivalent pursuant to 21 CFR 601.12(f)(4).

VI. TERMINATING SUBMISSION REQUIREMENTS

Under 21 CFR 314.560 and 601.46, FDA may determine after approval that the requirements established in §§ 314.550 and 601.45 are no longer necessary for the safe and effective use of a drug or biological product. If this happens, the Agency will notify the applicant in writing that advanced submission of promotional materials is no longer required. For human prescription drugs, the applicant will be notified by DDMAC in CDER. For biological products, the applicant will be notified by APLS in CBER.