

or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: August 10, 1994.

Linda A. Suydam,

Interim Deputy Commissioner for Operations.

[FR Doc. 94-19984 Filed 8-15-94; 8:45 am]

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Advisory Committee Meeting; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the agenda of the joint subcommittee meeting of the Nonprescription Drugs Advisory Committee and Arthritis Advisory Committee on Over-the-Counter Internal Analgesic, Antipyretic, and Antirheumatic Drug Products, which was announced in the Federal Register of July 11, 1994 (59 FR 35375). The change is being made to add an additional topic for discussion. There are no other changes. This amendment will be announced at the beginning of the open portion of the meeting.

FOR FURTHER INFORMATION CONTACT: Lee L. Zwanziger, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4695.

SUPPLEMENTARY INFORMATION: In the Federal Register of July 11, 1994, FDA announced that a joint subcommittee meeting of the Nonprescription Drugs Advisory Committee and the Arthritis Advisory Committee would be held on September 8 and 9, 1994. On page 35375, in the second column, the "open committee discussion" portion of this meeting is amended to read as follows:

Open committee discussion. On September 8 and 9, 1994, the joint subcommittee will discuss effectiveness data requirements and proposed labeling indications for OTC analgesic drug products. The joint subcommittee will address topics such as: (1) Data requirements to support specific types

of indications for OTC analgesic drug products; (2) recommendations for labeling indications for OTC analgesics; and (3) the current state of scientific knowledge in the areas of pain receptors, mechanism(s) of pain perception, and the basis for response to analgesic drug classes. On the afternoon of September 9, 1994, the joint subcommittee will also discuss the proposed changes in the format of labeling for OTC drug products.

Dated: August 10, 1994.

Linda A. Suydam,

Interim Deputy Commissioner for Operations.

[FR Doc. 94-20064 Filed 8-15-94; 8:45 am]

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Advisory Committee Meeting; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Generic Drugs Advisory Committee with Dermatologic Drugs Advisory Committee representation. This meeting was announced in the Federal Register of July 27, 1994 (59 FR 38196). The amendment is being made to add an agenda item for discussion on Tuesday, September 13, 1994. There are no other changes. This amendment will be announced at the beginning of the open portion of the meeting.

FOR FURTHER INFORMATION CONTACT: Kimberly L. Topper, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455.

SUPPLEMENTARY INFORMATION: In the Federal Register of July 27, 1994, FDA announced that a meeting of the Generic Drugs Advisory Committee with Dermatologic Drugs Advisory Committee representation would be held on September 12 and 13, 1994. On page 38196, in the third column, under *Open committee discussion* the agenda for the meeting is amended to read as follows:

Open committee discussion. In April 1992, the Generic Drugs Advisory Committee met to consider methods for documenting the bioequivalence of topical corticosteroids. Subsequently, on July 1, 1992, the Office of Generic Drugs issued a guidance document entitled "Interim Guidance for Topical Corticosteroids: *In Vivo* Bioequivalence and *In Vitro* Release Methods." The purpose of the September 1994 meeting

is to reexamine the 1992 interim guidance in light of new experimental data and methods of analysis. On September 12, 1994, the committee will discuss the pharmacodynamic (i.e., vasoconstrictor) measurement of bioequivalence. On September 13, 1994, this topic will be further discussed along with other issues related to the documentation of equivalence according to the interim guidance. Discussion will be limited to dermatologic products and will not include ophthalmic or inhaled corticosteroid products. Pilot data will be presented on the development of pharmacodynamic and pharmacokinetic assays to demonstrate tretinoin bioequivalence. Also, on September 13, 1994, there will be a review of the current status of topics discussed at previous Generic Drugs Advisory Committee meetings.

Dated: August 10, 1994.

Linda A. Suydam,

Interim Deputy Commissioner for Operations.

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National Institutes of Health

Meeting; Forum on Cooperative Research and Development Agreements

Notice is hereby given that a second Forum on Cooperative Research and Development Agreements (CRADAs), convened as an *ad hoc* group of consumer consultants to the Advisory Committee to the Director, NIH, will meet in public session on September 8, 1994, from 8:30 am to 5:30 pm, at the Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, Maryland, 20814. This Forum is convened in follow-up to a previous Forum on this topic July 21, 1994.

The purpose of the second Forum is to elicit consumer and other public interest perspectives which will be used in NIH's development of policy on the "reasonable pricing" clause, which is currently required in its Cooperative Research and Development Agreements (CRADAs) under the Federal Technology Transfer Act of 1986 and exclusive commercialization licenses. The Forum Panel members will discuss how best to ensure that the public investment in products developed through licensing NIH technologies is adequately reflected. Discussion will include an analysis of the clause and the Panel will advise on whether the clause has been useful to ensure that the public investment in collaborative research is adequately considered in the