McNeil, M.D.; Walter J. McNerney, M.H.A.; Edward B. Perrin, Ph.D; Louis F. Rossiter, Ph.D.; Albert L. Siu, M.D.; and Ellen B. White, M.B.A.

There also are Federal ex-officio members. These members are: Administrator, Substance Abuse and Mental Health Services Administration; Director, National Institutes of Health; Director, Centers for Disease Control and Prevention; Administrator, Health Care Financing Administration; Commissioner, Food and Drug Administration; Assistant Secretary of Defense (Health Affairs); and Chief Medical Director, Department of Veterans Affairs.

II. Agenda

On Thursday, May 30, 1996, the meeting will begin at 9:00 a.m. with the call to order by the Council Chairman. The Administrator, AHCPR, will update the status of current Agency issues and program initiatives. The Council will then discuss issues concerning the guideline program, public/private sector collaboration, and improvements to the large grant program. The Council will recess at 3:45 p.m. The Council will begin the closed portion of the meeting to review grant applications from 4:00 p.m. to 5:00 p.m.

The meeting will adjourn at 5:00 p.m. Agenda items are subject to change as priorities dictate.

Dated: May 8, 1996.

Clifton R. Gaus,

Administrator.

[FR Doc. 96–12066 Filed 5–13–96; 8:45 am]

BILLING CODE 4160–90–M

Administration for Children and Families

Agency Recordkeeping/Reporting Requirements Under Emergency Review by the Office of Management and Budget (OMB)

Title: Request for Emergency OMB Approval of Information Collection Under the Paperwork Reduction Act.

OMB No.: New.

Description: The State and Tribal JOBS plans are statutorily mandated and serve as the agreement between the State or the Tribal grantee and the Federal government for how JOBS programs will operate. The State/Tribal plans provide assurances that the JOBS program will be administered and operated in conformity with titles IV–A and IV–F of the Social Security Act, pertinent Federal regulations, and other applicable instructions or guidelines issued by ACF. This new State and Tribal JOBS plan section is being added in response to the President's recent directive requiring States to address the needs of teen parents so that they stay in school and become self-sufficient.

Respondents: State, Local or Tribal Govt.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Tribal JOBS	76	1	5	380
State JOBS	54	1	5	270

Estimated Total Annual Burden Hours: 650.

Additional Information

ACF is requesting that OMB grant a 90 day approval for this information collection under procedures for emergency processing by May 9, 1996. A copy of this information collection, with applicable supporting documentation, may be obtained by calling the Administration for Children and Families, Reports Clearance Officer, Roberta Katson at (202) 401–5756.

Comments and questions about the information collection described above should be directed to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paperwork Reduction Project, 725 17th Street NW., Washington, DC 20503, (202) 395–7316.

Dated: May 8, 1996.

Roberta Katson,

Director, Office of Information Resource Management Services.

[FR Doc. 96–11946 Filed 5–13–96; 8:45 am]

BILLING CODE 4184–01–M

Food and Drug Administration

FDA Form 3439, Interim Form for Application to Market a New Drug, Biologic, or Antibiotic Drug for Human Use; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of FDA Form 3439 entitled, ''Application to Market a New Drug, Biologic, or Antibiotic Drug for Human Use.'' This form is intended for use by applicants for licenses for specified biotechnology and specified synthetic biological products. FDA Form 3439 has received interim approval from the Office of Management and Budget (OMB) for use by applicants pending the availability of a harmonized form for use by applicants requesting approval of drugs, biological products, and antibiotics. The development of the harmonized form and this action are part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiatives.

EFFECTIVE DATE: The FDA Form 3439 may be used May 24, 1996.

ADDRESSES: Submit written requests for single copies of FDA Form 3439 to Division of Congressional and Public Affairs (HFM–44), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The form may also be obtained by FAX by calling the CBER Voice Information System at 1–800–835–4709. FDA Form 3439 is available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Annette A. Ragosta, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: FDA is making available FDA Form 3439, Application to Market a New Drug,

Biologic, or Antibiotic Drug for Human Use, for use in accordance with part 601 (21 CFR part 601), by applicants for licenses for specified biotechnology and specified synthetic biological products. In the final rule, ''Elimination of Establishment License Application for Specified Biotechnology and Specified Synthetic Biological Products,'' published elsewhere in this issue of the Federal Register, FDA is amending § 601.2 (a) and adding new § 601.2 (c) to create a licensing scheme for specified biotechnology and specified synthetic biological products. The final rule requires an applicant seeking marketing approval for specified biotechnology and specified synthetic biological products to submit a single biologics license application to CBER. FDA Form 3439 has received interim approval from OMB for use by applicants subject to the above-referenced final rule.

In the November 1995 report entitled, ''Reinventing the Regulation of Drugs Made from Biotechnology'' report, the President and Vice-President announced a series of regulatory reform initiatives, including FDA's intention to use a single harmonized application form for all licensed biological products and all drug products. The harmonized form will be made available for public comment and submitted to OMB for review and approval. FDA also intends to develop guidance to assist applicants in completing the harmonized application. Once it is approved for use by OMB, the harmonized form will supersede FDA Form 3439. Until that time, applicants for licenses for specified biotechnology and specified synthetic biological products may use the interim FDA Form 3439.

Under the Paperwork Reduction Act of 1995 (Pub. L. 104–13), all forms requesting a collection of information on identical items from 10 or more public respondents must be approved by OMB and must display a valid OMB control number and expiration date. FDA Form 3439 was approved under OMB control number 0910–0316. The expiration date for the form is December 31, 1997.

Dated: May 9, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–12145 Filed 5–10–96; 10:13 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0227]

Direct-to-Consumer Promotion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is publishing a notice making clear that the agency does not require preclearance of prescription product promotion (advertising and promotional labeling) of human or animal drugs, biologics, or restricted medical devices directed toward consumers. FDA is also requesting comments on its intent to consider certain FDA-approved patient labeling as adequate to fulfill the brief summary requirement in consumer-directed advertisements. Finally, FDA is soliciting comments concerning several issues related to consumer-directed promotion of prescription biologics, human and animal drugs, and restricted medical devices to help guide policy decisions.

DATES: Written comments by August 12, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nancy M. Ostrove, Division of Drug Marketing, Advertising and Communications (HFD–40), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, rm. 17–B04, Rockville, MD 20857, 301–827–2828, or via Internet at Ostrove@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Federal Food, Drug, and Cosmetic Act (act) and the Public Health Service Act, the Food and Drug Administration (FDA) has responsibility for regulating the labeling and advertising of prescription drugs (animal and human), biologics, and restricted medical devices. Labeling and advertising must follow certain requirements, as defined by the Act and implementing regulations.

Under section 502(n)of the act (21 U.S.C. 352(n)), an advertisement for a prescription drug must contain, in addition to the product's established name and quantitative composition, ''such other information in brief summary relating to side effects, contraindications, and effectiveness * * *.'' This requirement is further defined in prescription drug advertising regulations at § 202.1(e) (21 CFR 202.1(e)). Under section 502(r) of the act (21 U.S.C. 352(r)), an advertisement for a restricted medical device must contain, in addition to the established name, ''a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications * * *.''

The act and FDA's advertising regulations do not distinguish between targeted audiences. FDA recognizes, however, that there are differences between the information needs of health care professionals and consumers resulting from differences in medical and pharmaceutical expertise, and differences in roles as potential recipients of medications or prescribers of medications, that may affect their perceptions, comprehension, and interpretation of promotional claims. In light of these differences, FDA is continuing to evaluate its policies and regulations.

In the Federal Register of August 16, 1995 (60 FR 42581), FDA announced a part 15 (21 CFR part 15) hearing to be held on October 18 and 19, 1995. In that document, the agency solicited oral testimony and written responses to a series of questions concerning direct-to-consumer (DTC) promotion of prescription drugs. At the hearing, the agency heard testimony from representatives of consumer and patient groups, advertising associations, and foreign governments, as well as from individual academicians, attorneys, marketers, and pharmaceutical manufacturers. The agency accepted written comments until December 29, 1995. FDA is currently evaluating the testimony, comments, and issues raised by both the public hearing and citizen petitions submitted prior to the hearing.

While this evaluation proceeds, FDA is providing clarification of two of its policies and soliciting additional information to help in the development of overall policy. FDA views these efforts as part of a comprehensive process designed to encourage meaningful communication to consumers about prescription drugs, biologics, and restricted medical devices, while continuing to help ensure that consumers are adequately protected from false, misleading or otherwise violative promotion.

II. Preclearance

One issue raised in oral testimony, written comments, and citizen petitions was an objection to the perceived requirement for manufacturers to obtain prior clearance from the agency for all prescription drug and biological DTC promotion. There is, in fact, no such requirement. Given public and congressional concern since the early 1980's about prescription drug DTC promotion, together with the inexperience of the pharmaceutical industry in producing DTC advertising, FDA had informally requested manufacturers to submit, on a voluntary basis, proposed DTC promotional