regulations be amended to provide for the safe use of sucrose esterified with medium and long chain fatty acids as a replacement for fats and oils. (The additive is commonly referred to as olestra.) Since its filing, FDA has had the petition under active review, and the agency is in the final stages of its safety review of the additive.

In the Federal Register of October 17, 1995 (60 FR 53790), FDA announced that a public meeting of the agency's Food Advisory Committee (FAC) and a working group of the FAC would be held on November 14 through 17, 1995. The working group will undertake a scientific discussion of the safety review that has been conducted for olestra for its intended use as a fat replacer in savory snacks. The working group will be asked to comment on whether all relevant issues associated with olestra have been addressed. The discussion will cover all aspects of the safety review, including nutrient effects and compensation, gastrointestinal effects, and labeling. The recommendation of the olestra working group will be formally referred to the agency, along with any amendatory comments of the FAC. The agency will make the final determination on the olestra food additive petition. (See 21 CFR 14.5).

Consistent with the Federal Advisory Committee Act (5 U.S.C. App. 2), and the agency's regulations in part 14 (21 CFR part 14), the meeting of the working group and the FAC will be open to the public. In addition, as provided for in § 14.25, there will be an opportunity for public participation, including an opportunity for members of the public to present their views on the safety review of olestra, before both the working group and the FAC.

Under the Federal Food, Drug, and Cosmetic Act (the act), FDA is required to announce the filing of a food additive petition (21 U.S.C. 348(b)(5)). Although public notice of a petition is required, the act is silent with respect to public comment on a petition, and thus, the act provides no defined period for such comments. Accordingly, the filing notice did not expressly request comments on Procter & Gamble's petition. Nevertheless, written comments could have been, and in fact, have been submitted to the agency.

As noted above, FDA is in the final stages of review of the olestra food additive petition. Unless significant new safety issues are raised or important new data are submitted in the course of the advisory committee process, the agency will very likely conclude its review and be prepared to render a decision on Procter & Gamble's petition within approximately 2 months of the conclusion of the FAC meeting. To facilitate this decisionmaking process and the agency's coming to closure on the petition, FDA believes that it is important to identify precisely which data and information the agency will consider in making its decision on the petition. Absent such boundaries, it will be difficult for FDA to reach a decision because the underlying data set could be shifting continuously. (See *Sierra Club* v. *Costle*, 657 F.2d 298, 399–400 (D.C. Cir. 1981) (a participant's mere wish for additional time to respond to documents in the record to which it already had opportunity to respond cannot force an agency to delay process because new information may be forthcoming; otherwise participants could delay the process indefinitely because new information continually comes to light on the subject of many proposed rules.))

Given the importance of reaching a decision and the clear public interest in a decision, FDA has determined that any data, information, or comments received after December 1, 1995, will not be considered by the agency in determining whether to approve the petition. Any data, information, or comments received after that date will be filed in an administrative file and will be evaluated along with any objections to the final decision filed under 21 U.S.C. 348(f).

FDA believes that it is appropriate for the agency to manage its administrative processes, see *Sierra Club* v. *Gorsuch*, 715 F.2d 653, 658 (D.C. Cir. 1983)) (agency has control over timetable of rulemaking and such decisions are entitled to considerable deference); *Cutler* v. *Hayes*, 818 F.2d 879, 896 n. 150 (D.C. Cir. 1987), citing *Natural Resources Defense Council, Inc.* v. *SEC*, 606 F.2d 1031, 1056 (D.C. Cir. 1979) (agency is cognizant of the most effective structuring and timing of proceedings to resolve competing demands over its resources), and that in these circumstances, such management through defining a comment period will not unnecessarily limit public participation in that process.

In particular, for over 8 years, since the June 1987 publication of the filing notice, the public has been aware that the food additive petition for olestra has been under consideration by FDA, and has had the opportunity to submit information and comments to the agency on Procter & Gamble's proposal. In addition, under the applicable regulations (21 CFR 171.1(h)(1)(i)), all safety and functionality data for olestra submitted during this period by Procter & Gamble have been available to the public for review and comment upon the submission of such data to the agency. Interested persons have utilized this opportunity to review these data and to provide the agency with their views by submitting written comments. Finally, the agency has announced a public advisory committee meeting on the olestra petition. This meeting will provide interested persons with the opportunity to hear an informed scientific discussion of the relevant safety issues, and to present data, information, and views relevant to the safety of olestra.

The agency believes that with the conclusion of the FAC meeting, there will have been more than a reasonable opportunity for the public to provide data and information and to comment on the olestra food additive petition. See *Forester* v. *CPSC*, 559 F.2d 774, 787 (D.C. Cir. 1977). Because there has been such an opportunity, FDA believes that it is appropriate and consistent with the public interest to define a specific period for the submission of data, information, and comments on the food additive petition. Defining boundaries for those data, information, and comments to be considered by FDA in rendering a decision on the petition will facilitate the agency's coming to closure on this petition. Therefore, the agency is establishing December 1, 1995, as the date by which all data, information, and comments on the olestra food additive petition, including comments on the proceedings before the FAC, must be submitted to the agency in order to be considered by the agency in its decision on the petition.

Any request for extension of this period for comments on the olestra food additive petition should conform to the provisions of 21 CFR 10.40(b).

Dated: November 13, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–28359 Filed 11–13–95; 4:16 pm]

BILLING CODE 4160–01–F

Substance Abuse and Mental Health Services Administration

Changes to the Testing Cutoff Levels for Opiates for Federal Workplace Drug Testing Programs

AGENCY: Substance Abuse and Mental Health Services Administration, PHS, HHS.

ACTION: Notice of proposed revisions.

SUMMARY: The Department of Health and Human Services (HHS) is proposing to revise the Mandatory Guidelines for Federal Workplace Drug Testing Programs, 59 FR 29916 (June 9, 1994).

Specifically, the Department is proposing to change the drug testing levels currently used to test for opiate metabolites in urine specimens collected as part of the Federal Workplace Drug Testing Program and to require the testing for a metabolite of heroin. The goals of the proposed new opiate testing policy are to substantially reduce the number of laboratory opiate positives that Medical Review Officers ultimately verify as negative, shift the emphasis of opiate testing back to the proper focus to deter and detect heroin use, and reduce any unnecessary/excessive costs to drug testing without compromising the original drug deterrent objectives.

DATES: Comments on these proposed revisions to the Mandatory Guidelines are invited and must be submitted by January 16, 1996.

ADDRESSES: Written comments should be addressed to Joseph H. Autry III, M.D., Director, Division of Workplace Programs, SAMHSA, Room 13A–54, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Dr. Donna M. Bush, Chief, Drug Testing Section, Division of Workplace Programs, SAMHSA/CSAP, Room 13A–54, 5600 Fishers Lane, Rockville, Maryland 20857, tel. (301) 443–6014.

SUPPLEMENTARY INFORMATION: The Department proposes increasing the initial and confirmatory testing cutoff levels for morphine and codeine from 300 ng/mL to 2,000 ng/mL and establishing a new requirement to test for 6-acetylmorphine (6-AM), a metabolite that comes only from heroin, using a 10 ng/mL confirmatory level for specimens that have tested positive on the initial test. When the Federal Workplace Drug Testing Program was established, HHS adopted the same 300 ng/mL testing levels for opiates that were used by the Department of Defense for testing service members. These levels were selected in an attempt to provide the greatest opportunity to identify anyone who may have used heroin; however, at the 300 ng/mL level, many who have not used heroin but had taken a prescribed codeine or morphine medication or eaten normal dietary amounts of poppy seeds have also tested positive. Since the purpose of the drug testing program is to deter or detect individuals using illicit drugs, establishing the testing cutoff levels for opiates at the proposed 2,000 ng/mL and adding the requirement to detect 6-AM will eliminate the identification of most persons legitimately using opiate-containing pharmaceuticals available by medical prescription or in over-the-counter preparations, or those who have ingested poppy seeds. The Department of Defense adopted similar increases in the testing cutoff levels for opiates effective April 1, 1994, because of similar concerns and its program experience over the last 5 years. Changing the levels for the Federal Workplace Drug Testing Program will have similar direct effect as evidenced by the results obtained from several Medical Review Officers and laboratories regarding the large number of laboratory positives that were verified negative by MROs. In addition, the results indicate that specimens screened positive at or above the proposed 2,000 ng/mL testing cutoff levels for opiates are the specimens most likely to contain 6-acetylmorphine, a metabolite of heroin.

The Department has evaluated results on over 1.1 million urine specimens tested for opiates in 5 certified laboratories and approximately 317,500 specimens that were reviewed by 3 different Medical Review Officer (MRO) groups. Each laboratory and MRO group was asked to furnish information on results reported from January 1, 1992, to March 31, 1993. Based on the information obtained from the MROs, 87% of all opiate positives reported by the laboratories were verified negative by the MRO based on the use of prescription medications, poppy seed consumption, no clinical evidence of heroin use, or other reason. It is clear that the current opiate testing cutoff levels are not properly identifying opiate drug abusers.

The results from the laboratories indicate that of the approximate 1.1 million specimens tested, 7294 specimens were reported positive for codeine and/or morphine. Of these positive specimens, 5931 had codeine and/or morphine concentrations less than 2,000 ng/mL. Within the group of 7294 opiate positives, 848 were also tested for 6-acetylmorphine (6-AM) with only 16 of these 848 being reported positive for 6-AM. Additionally, 14 of these 16 6-AM positives had morphine concentrations greater than 2,000 ng/mL.

When comparing information from other published studies, there was agreement that the presence of 6-AM is highly associated with morphine concentrations in excess of 2,000 ng/mL.

In light of these results, the Department is proposing to increase the initial test level for opiate metabolites to 2,000 ng/mL and the confirmatory test levels for morphine and codeine to 2,000 ng/mL. In addition, the Department is proposing to establish a requirement to test for 6-AM in specimens positive for opiates on the initial test using a 10 ng/mL confirmatory test level. 6-AM is a metabolite of heroin and no other medication or substance is known to produce it; therefore, its presence is positive proof of heroin use. Since 6-AM has a very short half-life (i.e., detectable for only a few hours after heroin use), it is essential that a laboratory use a sensitive analytical procedure to test for 6-AM. From the data available, it appears that 10 ng/mL is the lowest testing level that can reasonably be used to consistently and accurately identify and quantitate the presence of 6-AM. Additionally, the 10 ng/mL confirmatory test level for 6-AM is currently used by many laboratories that test for 6-AM after an MRO submits a request. The Department believes the proposed requirement to test for 6-AM will not increase the workload for a laboratory because setting the initial test level for opiate metabolites at 2,000 ng/mL will significantly reduce the number of specimens that will need to be confirmed for morphine, codeine, and 6-AM.

The Department believes that raising the testing levels for opiates and establishing a requirement to test for 6-AM does not reduce the deterrent value of the Federal Workplace Drug Testing Program, but rather shifts the emphasis of opiate testing back to the original focus to deter and detect use of illicit drugs, including heroin. A change in the testing cutoff levels, in conjunction with the addition of 6-AM testing, should provide more than adequate protection that heroin users will be detected. The cost to Federal agencies may be reduced since there will be fewer specimens screened positive hence, a reduction in the number of specimens sent to confirmatory testing. The laboratories will be reporting fewer opiate positives which will also reduce the time and cost for MROs to discuss use of legitimately obtained opiate containing preparations with individuals who have been tested positive by the laboratory.

The SAMHSA Drug Testing Advisory Board has discussed these results and has recommended adopting the new opiate testing cutoff levels described above.

INFORMATION COLLECTION REQUIREMENTS: There are no new paperwork requirements subject to the Office of Management and Budget approval under the Paperwork Reduction Act of 1980.

Dated: September 26, 1995.

Philip R. Lee,

Assistant Secretary for Health.

Dated: November 6, 1995.

Donna E. Shalala,

Secretary.

The following amendments are proposed to the Mandatory Guidelines for Federal Workplace Drug Testing Programs published on June 9, 1994 (59 FR 29916):

Subpart B

1. Section 2.4(e)(1) is amended by changing the initial test level for opiate metabolites appearing in the table from ''300'' to ''2,000'' and deleting footnote 1.

2. Section 2.4(f)(1) is amended by changing the confirmatory test levels for morphine and codeine appearing in the table from ''300'' to ''2,000.''

3. Section 2.4(f)(1) is amended by adding in the table under opiates a confirmatory test level for 6-Acetylmorphine at ''10 ng/mL.''

[FR Doc. 95–28273 Filed 11–13–95; 8:45 am]

BILLING CODE 4160–20–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

[Docket No. FR–3990–D–01]

Redelegation of Authority

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner.

ACTION: Notice of redelegation of authority.

SUMMARY: This notice redelgates authority from the Assistant Secretary for Housing—Federal Housing Commissioner to certain positions within the Office of the Federal Housing Administration Comptroller, for the purpose of executing documents to effectuate the transfer of title to Title I loans sold by the Department of Housing and Urban Development.

EFFECTIVE DATE: November 7, 1995.

FOR FURTHER INFORMATION CONTACT: William Richbourg, Director, Management Control Staff, U.S. Department of Housing and Urban Development, 451 7th Street, SW., Room 5144, Washington, DC 20410, telephone (202) 401–0577. A telecommunications device for the hearing-impaired (TDD) is available at 202–708–4594. (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION: On July 7, 1994, at 59 FR 34857, the Assistant Secretary for Housing-Federal Housing Commissioner redelegated to the Director, Office of Mortgage Insurance Accounting and Servicing, Office of the FHA Comptroller, at headquarters, and to each of the Directors of the three HUD FHA Debt Management Centers, in the field, certain authority with regard to debt arising from the payment of claims under Title I of the National Housing Act. Among other things, they were granted the authority to execute documents necessary to transfer or subordinate title in and to any debt, contract, claim or security instrument obtained by the Secretary, and to satisfy and/or execute deeds, liens and notes.

FHA is now in the process of engaging in a sale of approximately 16,000 Title I notes, based upon sealed bids which are to be opened November 7, 1995. In order to effectuate the transfer of these specified Title I loans, it is necessary to provide additional HUD employees with the authority to execute all of the necessary documents. Among other things, these employees will have the authority to execute powers of attorney to enable the purchaser(s) to assign the Title I loans to themselves. In addition, FHA may engage in future sales of Title I loans, which will again require the assistance of these HUD employees.

Accordingly, the Assistant Secretary for Housing—Federal Housing Commissioner redelegates authority as follows:

Section A. Authority Redelegated

The Director, Office of Mortgage Insurance Accounting and Servicing; the Director, Title I Accounting and Servicing Division; the Deputy Director, Title I Accounting and Servicing Division; the Chief, Title I Operations Branch; the Chief, Title I Notes Branch; and the Director, Management Control Staff, all of the Office of the Federal Housing Administration Comptroller, are each redelegated the power and authority to execute all documents necessary to effectuate the transfer of title in and to Title I loans sold by the Department of Housing and Urban Development. This redelegation includes, but is not limited to, the authority to execute powers of attorney to enable the purchaser or purchasers of the loan to execute the necessary assignments of notes, and mortgages or deeds of trust.

Section B. Limited Authority to Further Redelegate

The authority granted in Section A., above, may be further redelegated in writing by the Director, Office of Mortgage Insurance Accounting and Servicing, pursuant to this redelegation. The authority granted in Section A. may not be further redelegated by any of the other officials listed within Section A.

Authority: Sec.7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d).)

Dated: November 7, 1995.

Nicolas P. Retsinas,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 95–28281 Filed 11–15–95; 8:45 am]

BILLING CODE 4210–27–M

Office of the Assistant Secretary for Policy Development and Research

[Docket No. FR–3825–N–03]

Announcement of Funding Awards for Fiscal Year 1995 Community Outreach Partnership Centers

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Announcement of funding awards.

SUMMARY: In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this document notifies the public of funding awards for Fiscal Year 1995 Community Outreach Partnership Centers Program. The purpose of this document is to announce the names and addresses of the award winners and the amount of the awards which are to be used to establish and operate Community Outreach Partnership Centers that will: (1) Conduct competent and qualified research and investigation on theoretical or practical problems in large and small cities; and (2) facilitate partnerships and outreach activities between institutions of higher education, local communities, and local governments to address urban problems.

FOR FURTHER INFORMATION CONTACT: Marcia Marker Feld, Ph.D., Director, Office of University Partnerships, U.S. Department of Housing and Urban Development, room 8130, 451 Seventh Street, SW, Washington, DC 20410, telephone (202) 708–3061. To provide service for persons who are hearing- or speech-impaired, this number may be reached via TDD by dialing the Federal Information Relay Service on 1–800–877–TDDY, 1–800–877–8339, or 202–708–9300. (Telephone numbers, other than ''800'' TDD numbers are not toll free.).

SUPPLEMENTARY INFORMATION: The Community Outreach Partnership