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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Supplemental Standards of Ethical Conduct and Financial Disclosure Requirements for Employees of the Department of Health and Human Services

AGENCY: Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services, with the concurrence of the Office of Government Ethics (OGE), is amending the HHS regulation that supplements the OGE Standards of Ethical Conduct. This final rule adopts, with certain revisions, the changes made to 5 CFR part 5501 in the interim final rule that was published on February 3, 2005, at 70 FR 5543. After considering comments to that rulemaking, this final rule: Clarifies the definition of an ''employee of a component;'' Amends the outside activity prior approval requirements applicable to employees of the Food and Drug Administration (FDA) and the National Institutes of Health (NIH); Revises prior approval information collection requirements and the waiver provision applicable to the outside activities prohibitions; Removes professional associations and other science and health-related organizations from the list of entities with which NIH employees are prohibited from engaging in outside activities; Adds exceptions to the NIH outside activities prohibition for delivering a class lecture as part of a regularly scheduled university course, serving on data and safety monitoring boards and grant and scientific review committees, and presenting in Grand Rounds; Limits the prohibition on holding financial interests in substantially affected organizations to senior NIH employees, their spouses, and minor children only, permits investments in such organizations that do not exceed $15,000, and allows holdings capped at $50,000 in sector mutual funds that concentrate their investments in the securities of substantially affected organizations; and Revises the outside award limitations for senior NIH employees by applying an official responsibility test for matters potentially involving an award donor. In addition, the financial disclosure reporting requirements specified in new part 5502 that were added by the interim final rule of February 3, 2005, at 70 FR 5543, and amended by an interim final rule that was published on June 28, 2005, at 70 FR 37009, are adopted as final, subject to certain amendments. The requirement to file a supplemental disclosure of financial interests in substantially affected organizations is refocused to apply to NIH employees who file a public or confidential financial disclosure report and other NIH employees who are designated as investigators in an NIH clinical research protocol approved by an institutional review board. The due date for the initial report is also changed.

DATES: This final rule is effective August 31, 2005.

FOR FURTHER INFORMATION CONTACT: Edgar M. Swindell, Associate General Counsel, Office of the General Counsel, Ethics Division, Department of Health and Human Services, telephone (202) 690–7258, fax (202) 205–9752.

SUPPLEMENTARY INFORMATION:

I. Background

The Standards of Ethical Conduct for Employees of the Executive Branch, 5 CFR part 2635, establish uniform rules of ethical conduct applicable to all executive branch personnel. Pursuant to 5 CFR 2635.105, an agency may, with the approval of the Office of Government Ethics, supplement those standards with additional rules that the agency determines are necessary and appropriate, in view of its programs and operations, to fulfill the purposes of part 2635. On July 30, 1996, with the concurrence and co-signature of the OGE Director, HHS published at 61 FR 39755 a final rule codified at 5 CFR part 5501 establishing supplemental standards of ethical conduct for its employees. The 1996 final rule was amended by an interim final rule with a request for comments that was published at 70 FR 5543 on February 3, 2005.

The interim final rule focused primarily on rules applicable to employees of the National Institutes of Health related to outside activities, financial holdings, and awards. Regulatory action was taken to address significant concerns about employee conduct in those areas which had been the subject of media reports and Congressional hearings. The resulting provisions generated considerable comment and prompted press coverage of employee objections, possible adverse effects on hiring and retention, and public reaction across a broad spectrum of viewpoints. The comments have been carefully considered and will be addressed more specifically below.

In addition, the Executive Branch Financial Disclosure Regulation, 5 CFR part 2634, specifies uniform rules governing the public and confidential financial disclosure systems established under the Ethics in Government Act. Pursuant to 5 CFR 2634.103, an agency may, subject to the prior written approval of the Office of Government Ethics, issue supplemental financial disclosure regulations that are necessary to address special or unique circumstances. The interim final rule amended chapter XLV of title 5 by adding new part 5502 to provide for an annual reporting by all employees of financial and other information concerning outside activities and a supplemental disclosure by all FDA and NIH employees with respect to prohibited financial interests. The latter disclosure requirement for NIH employees is being changed to correlate with revisions to the prohibited holdings rule.

Although this rulemaking confirms as final, with significant revisions, the amendments made by the interim final rule, the regulation will be reviewed within one year to evaluate its continued adequacy and effectiveness in relation to current agency responsibilities. As indicated in the preamble to the interim final rule at 70 FR 5543, those aspects of the rule governing outside activities continue to be under review for the remainder of the year indicated in that discussion.

II. Summary of Comments

Approximately 1200 of the more than 1400 comments timely submitted were from NIH employees, and about 70 comments were submitted by spouses and other family members of NIH employees. The remaining comments were submitted by health care professionals and scientific investigators at various universities and health care facilities, and a number of private sector entities, such as professional associations, other non-profit organizations, and corporations. The Department of Health and Human Services has considered each of the comments received. Those determined to be significant are discussed in further detail below in the context of the sections to which they pertain.

Many commenters submitted their views on more than one provision, and some provided multiple observations about a single provision. About 365 comments specifically addressed the outside activity limitations, and slightly more, about 385, focused on the prohibited holdings rule. The awards provision generated no specific reaction.

With respect to outside activities, some commenters objected to the increased paperwork and administrative burden that would be generated by the expanded prior approval requirement. They also expressed a more generalized concern that the restrictions would stifle the ability of government scientists to interact with their private sector counterparts, thus depriving them of personal and professional development opportunities and slowing the translation of scientific discoveries into tangible benefits for the public.

Regarding the prohibited holdings provision, many commenters questioned the relative fairness of the regulatory approach and its application to all NIH employees as well as their spouses and minor children. Some commenters who understood the need to divest holdings in substantially affected organizations urged a longer grace period within which to comply.

A number of intramural NIH employees, collectively known as the Assembly of Scientists, and others recommended as an alternative to the interim final rule that conduct provisions be established for each of several groups or categories of employees. The five or other number of categories recommended were intended to represent large groups of employees with relatively similar duties and authorities. Applicable rules would be tailored to each category in an effort to respond to the issues of greatest risk for each group. While the Department did not wholly accept these proposals, a number of revisions are being made in recognition of the differences between employees as to rank, duties, and their level of responsibility for matters affecting public health and clinical research protocols involving human subjects.

Comments, either of style or substance, that were generally supportive or generally critical of the interim final rule are not discussed in detail. The latter category of comments far exceeded the former, but a few commenters expressed support for the rule asserting that the provisions would reduce or eliminate financial motives that might be perceived as influencing scientific and medical research. Those submissions that offered no constructive comments, but simply inquired about the application of the interim final rule to the commenter's own situation, such as whether a particular company was a significantly affected organization or whether an aspect of the rule applied to the commenter, are not addressed. Those comments that discussed topics unrelated to government ethics, pointed to implementation issues that have been resolved, or were without substantive merit are also not discussed. Nor does this discourse specifically refer to comments that demonstrated a clear misunderstanding of the purpose or language of the interim final rule or of other applicable government ethics laws or regulations, except when such comments highlighted the need for NIH-specific standards. Among such comments were those suggesting that the Government must compensate employees for the costs of complying with regulations intended to prevent financial conflicts of interest, statements that new laws could not legally change the rules for current NIH employees, comments suggesting that it would not be appropriate for the Department to hold NIH employees to any standard that exceeds the standards applicable to employees of non-governmental entities, and comments indicating an unawareness of the exceptions to the outside activity and awards provisions applicable to NIH employees and to the financial holdings provision applicable to NIH employees and their spouses and minor children. Finally, comments regarding the administration of the ethics program at the NIH that are unrelated to substance or procedures in the interim final rule are not addressed.

III. Analysis of the Amendments

A. Supplemental Standards of Ethical Conduct

Section 5501.101 General

Paragraph (c) is amended to provide that the terms used in part 5501, unless otherwise defined, have the same meaning as those defined in parts 2635 and 2640. The paragraph previously referred only to part 2635. The change reflects the use within § 5501.110 of several terms defined in part 2640, such as holdings, pension plan, and sector mutual fund.

Section 5501.102 Designation of HHS Components as Separate Agencies

The change to this section clarifies an ambiguity in § 5501.102(b)(1). The definition of ''employee of a component'' can be interpreted to apply the supplemental ethics rules applicable to a designated agency component to all employees of a division or region of the Office of the General Counsel if the division or region is principally responsible for advising or representing that component. This formulation does not comport with the current assignment of responsibilities within OGC. For example, regional offices have generalist, rather than component-specific responsibilities. Some divisions have multiple branches, and then only one branch within a division can be said to focus primarily on a particular component. Accordingly, § 5501.102(b)(1) is amended to focus on the regularly assigned duties and responsibilities of an individual employee rather than that person's location within the organization.

Section 5501.106 Outside Employment and Other Outside Activities

Section 5501.106(c)(3)(ii)(B) originally provided for an exception to the FDA prohibited outside activities rule to allow clerical or similar services (such as cashier or janitorial services) for retail stores, such as supermarkets, drug stores, or department stores, that might otherwise be significantly regulated organizations due to their sales of FDA-regulated products. As drafted, the exception applied only where clerical or similar services were performed for retail stores. An employee who worked on the weekends as a plumber could not respond to an emergency repair call to fix a leaky pipe at a bottling plant or a pharmaceutical manufacturing facility. Although seemingly innocuous business relationships can raise conflicts and impartiality concerns, subjecting such activities to an absolute prohibition with only a narrow exception tied to

employment at retail stores does not appear to be warranted.

With respect to the parallel provision governing NIH employees at § 5501.109, several commenters urged that appropriate exceptions be adopted to accommodate activities that pose a diminished risk for potential conflicts or other ethics concerns, such as performing plumbing or electrical work, providing protective or security services, and rendering other types of personal services that are unrelated to the substantive programmatic functions of their employing agency. The Department concurs in those comments and will apply the changes urged for NIH employees to FDA employees as well. Accordingly, this final rule revises the exception to the FDA prohibited outside activity rule at § 5501.106(c)(3) to permit employment that primarily involves manual or unskilled labor or utilizes talents, skills, or interests in areas unrelated to the substantive programmatic activities of the FDA, such as clerical work, retail sales, service industry jobs, building trades, maintenance, or similar services. For example, assuming the activity would not otherwise violate a Federal statute or regulation or result in recusals that would materially impair the employee's ability to do his government job, an FDA employee covered by the rule would be permitted to work as a cashier at a retail drug store and ring up consumer purchases of soft drinks and prescription drugs, or as a truck driver who delivers such products to the retailer. However, § 5501.106(c)(3) will continue to prohibit a public or confidential filer at FDA from serving as a salesman for a beverage distributor or as a pharmaceutical company representative engaged in wholesale transactions.

Section 5501.106(d)(2)(i) as amended by the interim final rule required FDA and NIH employees to obtain prior approval for any outside employment or self-employed business activity. Prior to the interim final rule, this requirement applied only to the FDA. A number of commenters objected to extending the requirement to the NIH, citing the increased paperwork and administrative burden. They claimed that the expanded prior approval requirement would discourage participation in outside activities and lead to a decrease in civic engagement in community groups, volunteer efforts, and non-profit organizations that allegedly pose no conflict of interest for NIH employees. Other commenters questioned the need to approve outside activities with no apparent connection to agency operations such as lawn mowing, teaching music, or selling real estate.

Prior to the interim final rule, NIH employees were required only to obtain prior approval to engage in an outside activity that involved providing professional or consultative services; teaching, speaking, writing, or editing that related to an employee's official duties under the government-wide standard, 5 CFR 2635.807, or that resulted from an invitation from a prohibited source; or serving as an officer, director, or board member. The interim final rule widened the scope of activities subject to prior approval for several reasons. Prior approval at the NIH was expanded primarily as a means to implement the prohibition in § 5501.109 on outside activities with substantially affected organizations (SAO), supported research institutions (SRI), health care providers or insurers (HCPI), or related trade, professional, or similar associations (RTPSA). An approval process that focused only on professional or consultative services, teaching, speaking, writing, editing, or board service would not screen for prohibited activities with SAOs, SRIs, HCPIs, or RTPSAs that fell outside those enumerated categories. Moreover, activities considered less problematic, such as clerical work, protective services, or building maintenance, even when performed for organizations other than SAOs, SRIs, HCPIs, or RTPSAs, potentially could violate other supplemental provisions. For example, an NIH employee cannot work as a child care provider at a local Head Start agency if the employee's salary is funded by an Administration for Children and Families (ACF) grant, or moonlight as a guard for a protective services contractor providing security for an FDA facility because § 5501.106(c)(2) bars compensated employment in an HHS-funded activity. Thus, absent an expanded prior approval requirement, an employee might engage unintentionally in proscribed conduct. Prior approval also provided additional opportunities for a ''teaching point'' where an individual employee could receive guidance about conflicts under 18 U.S.C. 208, appearance concerns under 5 CFR 2635.502, and the use of public office for private gain addressed in 5 CFR 2635.702. The restrictions on representing outside entities before the Government under 18 U.S.C. 203 and 205 also could be stressed.

Despite the benefits of requiring prior approval for all outside activities, many commenters questioned whether requiring advance permission to paint houses, teach piano, or coach a sports team, for example, was warranted. The Department concurs that such activities generally are unlikely to pose conflicts or other ethics concerns. Consideration was given to excluding these examples and a list of similar activities from the prior approval requirement using the existing authority in § 5501.106(d)(6), now codified as paragraph (d)(7). Upon further evaluation, the Department has decided to remove entirely the requirement that FDA and NIH employees must obtain prior approval for all outside activities.

In its place, paragraph (d)(2) has been revised to require an FDA or NIH employee to obtain prior approval for any outside employment, as defined in 5 CFR 2635.603(a), with, or any self-employed business activity involving the sale or promotion of products or services of, any person or organization that is a prohibited source of the employee's agency component. The term ''prohibited source'' is defined in 5 CFR 2635.203(d) as any entity that seeks official action from, does business or seeks to do business with, or conducts activities regulated by the employee's agency; has interests that may be substantially affected by the performance or nonperformance of the employee's official duties; or is an organization the majority of whose members are such entities. The Department has designated separate agency components in § 5501.102 that define an ''employee's agency'' for purposes of outside activity prior approval. The FDA and the NIH have been so designated.

As a result of the revised prior approval requirement, if an outside activity does not involve professional or consultative services; teaching, speaking, writing, or editing that relates to official duties; or board service; an FDA or NIH employee no longer needs prior approval, unless the activity involves employment undertaken at the invitation of or performed for a prohibited source of the FDA or the NIH respectively.

For FDA or NIH employees who previously were subject to a prior approval requirement for all outside activities, this distinction aligns the prior approval requirement more closely with those types of external entities that are most likely to pose conflicts or raise appearance concerns. By tailoring the prior approval requirement in this manner, however, not all potential violations will be detected, as was previously discussed. An NIH employee who seeks to moonlight as a guard at a Head Start grantee agency or for the contractor that provides protective services for FDA at the Parklawn

Building will not have to file an HHS 520 prior approval form because the grantee and contractor are prohibited sources of ACF and FDA respectively, rather than NIH. This omission necessitates extensive training regarding the existing prohibitions in §§ 5501.106(c)(1) and (2) which bar employees from receiving compensation for assisting in the preparation of documents to be submitted to HHS or working in an HHS-funded activity.

Nevertheless, this change in the prior approval requirement from that specified in the interim final rule considerably reduces the paperwork and administrative burden for FDA and NIH employees and their respective agencies, without unduly diminishing the ability of each agency to ensure compliance with applicable ethics laws and regulations. A prior approval requirement for FDA or NIH employees that focused on whether the proposed employment is to be conducted with a prohibited source of HHS, as opposed to the employee's own component, would be unnecessarily broad, given the extensive reach of the Department's operations in many sectors of the economy. Accordingly, this final rule correlates prior approval with those activities and sources of outside employment that have a more clearly demonstrable nexus to the employee's work and that of the employing agency and hence the potential for ethics concerns.

The prior approval exceptions for activities with political, religious, social, fraternal, or recreational organizations formerly contained in paragraphs (d)(1)(iii) and (d)(2)(ii) are now combined, placed in new paragraph (d)(3)(i), and made applicable to all categories within the general approval requirement in paragraph (d)(1), as well as to paragraph (d)(2). The addition of new paragraph (d)(3) necessitated the renumbering of the succeeding paragraphs.

The amended paragraphs (d)(4)(ii)(D) through (d)(4)(ii)(O) specify information to be supplied by an employee who requests prior approval to engage in an outside activity. These paragraphs were edited without substantive change, with the exception of a new paragraph (d)(4)(ii)(F), which caused the subsequent subparagraphs to be redesignated. The new subparagraph (F) elicits travel reimbursement information separately from compensation because travel reimbursement is treated differently under various ethics rules depending upon the employee's status and other circumstances. Subparagraph (I) is amended to focus solely on compensation and non-travel related cash or in-kind items.

Paragraph (e) is amended to clarify that the designated agency ethics official may grant a written waiver of the prohibited outside activity rules to either an individual or a class of similarly situated persons.

Section 5501.109 Prohibited Outside Activities Applicable to Employees of the National Institutes of Health

Under § 5501.109(c)(1) of the interim final rule, subject to certain exceptions, all NIH employees were prohibited from engaging in employment (which includes serving as an officer, director, or other fiduciary board member, serving on a scientific advisory board or committee, and consulting or providing professional services) and compensated teaching, speaking, writing, or editing with a substantially affected organization (SAO), a supported research institution (SRI), a health care provider or insurer (HCPI), or a related trade, professional, or similar association (RTPSA). Employees were also prohibited from engaging in any self-employed business activity that involves the sale or promotion of products or services of an SAO or HCPI.

A ''substantially affected organization'' was defined to include those entities, irrespective of corporate form, that are engaged in the research, development, or manufacture of biotechnological, biostatistical, pharmaceutical, or medical devices, equipment, preparations, treatments, or products. The term includes those organizations a majority of whose members are engaged in such activities, such as industry trade associations, and any other entity classified by the designated agency ethics official as a substantially affected organization.

A ''supported research institution'' was defined as an educational institution or a non-profit independent research institute that within the last year or currently has applied for, proposed, or received an NIH grant, cooperative agreement, research and development contract, or cooperative research and development agreement (CRADA).

A ''health care provider or insurer'' was defined comprehensively to include the types of entities that are eligible to receive payments under the Medicare program for the provision of health care items or services and those risk-bearing entities that offer health insurance or health benefits coverage.

A ''related trade, professional, or similar association'' referred to a trade, professional, consumer, advocacy, or other organization, association, society, or similar group that is significantly involved in advancing the interests of persons or entities engaged in activities related to or affected by the health, scientific, or health care research conducted or funded by the NIH.

The prohibited outside activities rules applicable to all NIH employees were intended to focus on those types of activities and external entities that may pose the most significant risk of potential conflicts. The need for prophylactic rules barring certain types of outside activities derived in part from the significant administrative burden inherent in case-by-case determinations and the difficulties encountered by non-scientific staff at NIH tasked with administering the ethics program. In order to advise whether an outside activity was related to an employee's official duties, the ethics staff often had to differentiate scientific work performed as an official duty assignment from that proposed as an outside activity, a technical task for which they lacked the requisite expertise. See the discussion in the preamble to the interim final rule at 70 FR 5548.

A number of commenters asserted that the translation of NIH discoveries into viable and available medical advances to improve the public health would be hampered by the restriction on outside consulting and other collaborations with industry. Given that the interim final rule contained no provisions limiting the ability of NIH employees to engage officially in efforts to advance NIH discoveries, or to travel in their official capacities to present and discuss research findings (at the expense of others where appropriate under NIH policy), and contained a specific exception permitting employees to engage in outside activities involving efforts to commercialize invention rights waived to them by the agency, the basis for those comments is unclear. No changes have been made in response to such comments.

Nevertheless, the Department has revised § 5501.109 to accommodate a significant number of comments from professional associations, constituent groups, university observers, employees and their families regarding the new restriction on employment, including consultation and board service, with ''related trade, professional or similar associations.'' Specifically, the comments expressed concern that restrictions imposed on the ability of NIH employees to participate fully as members of the greater scientific community would negatively affect the public health because NIH scientists would become isolated from their

counterparts in the private and academic sectors and ultimately a reduction in recruitment and retention at NIH would result. As noted in the preamble to the interim final rule at 70 FR 5549, the Department fully appreciates that scientific exchange between professionals is a cornerstone of the scientific process, and that science is a collaborative endeavor that necessitates interaction between experts in their respective fields.

Therefore, upon further consideration, outside activities with RTPSAs do not appear to raise the same concerns that underlie the prohibition on outside activities with SAOs, SRIs, and HCPIs. Although activities with health-related trade associations, such as those that represent health care providers or insurers, may present potential conflicts, the trade associations most directly interested in NIH research activities are those that represent the pharmaceutical, biotechnology, and medical device industries. Such trade associations are already covered by the prohibition on outside activities with SAOs due to the composition of their membership. In addition, serving as an officer or board member of, or consulting for, a professional association, an advocacy group, or a consumer organization, although not devoid of potential conflicts, presents financial interests and covered relationship issues distinct from those presented by employment or consulting with SAOs, SRIs, and HCPIs, the commercial interests of which are more directly affected by NIH research and funding activities. Consequently, in order to tailor more narrowly the scope of the outside activity prohibition, RTPSAs are deleted. Outside activities with RTPSAs that involve professional or consultative services, teaching, speaking, writing, editing, or board service or that are performed for a prohibited source of the employee's agency nevertheless require prior approval and are subject to the substantive provisions governing outside activities under prior existing law.

Section 5501.109(c)(3) of the interim final rule contained several exceptions designed to facilitate professional obligations and certain academic endeavors. These exceptions partially lifted the absolute bar on outside activities with the list of organizations described in § 5501.109(c)(1), but they did not affirmatively permit an activity that would otherwise violate Federal law or regulations, including 5 CFR parts 2635, 2636, and 5501. Specifically, exceptions were provided to allow, subject to the prior approval standard and the substantive provisions governing outside activities under prior existing law, participation in pursuits that are critical to maintaining technical proficiency, professional licenses, and academic credentials and disseminating scientific information, such as teaching involving multiple presentations at academic institutions, providing individual patient care, moderating or presenting at continuing professional education programs, and writing or editing scientific articles, textbooks, and treatises that are subjected to scientific peer review or a substantially equivalent editorial review process. The rule also contained exceptions for employment with, providing professional or consultative services to, or teaching, speaking, writing, or editing for, a political, religious, social, fraternal, or recreational organization. The rule also recognized that individuals may be employed in less problematic roles with outside entities such as providing clerical assistance, janitorial services, or unskilled labor.

The exception to the outside activity prohibition in § 5501.109(c)(3)(iii) for clerical or similar services is amended to correspond with the changes to the FDA counterpart to this provision at § 5501.106(c)(3)(ii)(B).

This final rule identifies four additional activities as exceptions to the outside activity prohibition in order to promote important educational objectives and advance public health and safety. As with the existing exceptions, any outside activity excepted from the prohibition in § 5501.109(c)(1) may be prohibited nonetheless if the activity would otherwise violate Federal law or regulations, including 5 CFR parts 2635, 2636, and 5501. With this caveat understood, two changes refine the existing exceptions for teaching and continuing professional education. Two other changes permit employees to serve, under certain circumstances, on data and safety monitoring boards associated with clinical research protocols and to lend their expertise on grant and scientific review committees for external funding institutions.

First, new § 5501.109(c)(3)(i)(B) permits compensation for a single class lecture delivered by the employee as part of a regularly scheduled course taught by an individual other than the employee at an accredited academic institution. Unlike the exception in paragraph (c)(3)(i)(A) for teaching a course involving multiple presentations, a compensated guest lecture delivered on a single occasion within the context of a college course is subject to the prohibition in 5 CFR 2635.807(a)(2)(i)(B) on accepting compensated teaching and speaking invitations extended primarily because of official position and the subject matter restrictions of 5 CFR 2635.807(a)(2)(i)(E). The latter provision refers to activities the subject matter of which deals in significant part with the employee's current or recent (within the last year) work assignments or any ongoing or announced policy, program, or operation of the agency. Similarly, the new exception for single lectures will not permit compensation for activity related to the employee's official duties within the meaning of any other provisions in 5 CFR 2635.807(a)(2)(i). Class lectures that would be prohibited as outside activities for these reasons may, in appropriate circumstances, be given as part of an employee's official duties with supervisory approval. Class lectures permissible as compensated outside activities would be those that result from invitations extended primarily because of the employee's expertise, that occur at universities lacking interests affected substantially by the employee's discharge of official duties, and that convey broad knowledge about a particular scientific or clinical area, and not those that focus on the employee's own work or other cutting-edge research conducted at the NIH.

Second, the current continuing professional education exception addresses only one aspect of the instructional continuum in the medical profession, *i.e.*, those seminars that are open to practicing physicians. Presentations geared to an audience composed of medical students and resident physicians-in-training, commonly known as Grand Rounds, are not covered, yet the educational interaction of NIH employees with this population is as critically important as participation in continuing medical education (CME) instruction, particularly given the potential to recruit attendees to work at the NIH. Accordingly, new paragraph (c)(3)(vii) incorporates a Grand Rounds exception with appropriate limitations to preclude participation in such activities if an SAO or speakers' bureau affiliated with an SAO sponsors the program or the employee's presentation other than through an unrestricted educational grant.

As with other exceptions in paragraph (c)(3), the exception for compensated Grand Rounds presentations is subject to the limitations in 5 CFR 2635.807. Accordingly, the invitation to deliver a Grand Rounds presentation cannot have been tendered to the employee primarily because of the employee's

official position or extended by an entity that has interests that may be substantially affected by the performance or nonperformance of the employee's official duties. The subject matter of the Grand Rounds presentation must not deal in significant part with the employee's recent (within the last year) or current assignments or any ongoing or announced policy, program, or operation of the NIH. The information conveyed may not draw substantially on ideas or official data that are nonpublic information.

Third, NIH employees often have played a critical role in serving on data and safety monitoring boards (DSMB) for clinical trials conducted at universities and medical research institutes. These boards monitor incoming statistical and other data on patient outcomes and adverse events that may be associated with a drug, biologic, or an intervention under review in a clinical trial. The DSMB members are experts in relevant disciplines, such as trial design, biostatistics, and bioethics, who are not directly involved in conducting the study. Although the DSMB members generally are considered a group separate from the sponsor (entity that funds the trial), the organizer (entity that selects the members), or the investigators (lead scientific staff that conducts the clinical research), DSMBs follow various models with respect to the degree of independence from the sponsor. See Arthur S. Slutsky *et al.*, *Data Safety and Monitoring Boards*, 350 N. Eng. J. Med. 1143 (2004); Food and Drug Administration, *Guidance for Clinical Trial Sponsors on the Establishment and Operation of Clinical Trial Data Monitoring Committees* (2001), draft guidance available at *http://www.fda.gov/cber/gdlns/clindatmon.pdf*; National Institutes of Health, *Further Guidance on Data and Safety Monitoring for Phase I and Phase II Trials* (2000), available at *http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html*; and National Institutes of Health, *NIH Policy for Data and Safety Monitoring* (1998), available at *http://grants.nih.gov/grants/guide/notice-files/not98-084.html*.

The exception is intended to facilitate DSMB service, while maintaining the restrictions if a substantially affected organization selects the members of the DSMB or pays for their service, or if the protocol is funded by the NIH. The exception is also unavailable if the activity would violate the HHS-wide prohibitions in 5 CFR 5501.106(c)(1) and (2) relating to the compensated preparation of documents intended for submission to HHS and working for pay on an HHS-funded activity.

Fourth, NIH employees also have served on grant and scientific review committees for private foundations and other grant-making entities to assist those institutions in awarding their own funds to qualified applicants. NIH employees lend their considerable expertise in judging scientific merit, project feasibility, and other factors. As a result of the interim final rule, private foundations that funded scientific research activities would have been considered an RTPSA inasmuch as they are organizations that are ''significantly involved in advancing the interests of persons or entities engaged in activities related to or affected by the health, scientific, or health care research conducted or funded by the NIH.'' 70 FR 5560. Serving on grant and scientific review committees for private foundations and other grant-making entities is in the public interest, even where done in a personal capacity. Accordingly, the rule is amended to provide an appropriate exception.

For the most part, permitting this activity has been accomplished by removing RTPSAs from the list of organizations described in § 5501.109(c)(1); however, because an SRI or an HCPI can also make grant awards, an exception in new paragraph (c)(3)(viii) is added. For example, a private foundation that makes research grants might itself receive a training or conference grant from the NIH and thus may be considered an SRI. Absent the exception, an employee might be precluded from serving on a body that assists the private foundation in awarding research grants. Similarly, a university or hospital within the SRI and HCPI categories might receive a donation or bequest intended for the purpose of making research grants. Those entities also may convene groups to advise on the selection of grantees.

The exception does not permit an employee to serve on a grant or scientific review committee for a grant award or program funded by the NIH. In addition, if the employee is paid to serve on a grant or scientific review committee, such service cannot involve the preparation of documents intended for submission to HHS within the meaning of § 5501.106(c)(1), and the grant award or program about which the committee provides input cannot be an HHS-funded activity as described in § 5501.106(c)(2). A further caveat is that a substantially affected organization cannot select the members of the grant or scientific review committee or pay them for their service. Provided that the funding institution retains control of member selection and payment, this caveat is not intended to preclude such service if a substantially affected organization provides an unrestricted grant to the funding institution.

Paragraphs (c)(4) and (c)(5), which provided a transitional grace period with an opportunity for an extension of time for terminating outside activities prohibited by paragraph (c)(1), are removed. The time periods calculated from the date of publication of the interim final rule, February 3, 2005, have passed, and such activities should now have ceased.

Section 5501.110 Prohibited Financial Interests Applicable to Employees of the National Institutes of Health

Section 5501.110 of the interim final rule prohibited employees of the NIH who file either a public or confidential financial disclosure report, and their spouses and minor children, from owning stock and having other financial interests in substantially affected organizations, subject to certain exceptions. All other NIH employees (as well as those confidential filers excluded from coverage by the rule) were subject to a $15,000 limit on the holding or acquisition of such interests and certain other restrictions. All NIH employees were permitted to invest freely in widely diversified, publicly traded mutual funds, even if those funds owned shares in substantially affected organizations. The rule also allowed spouses, and employees who came from industry, to retain financial interests derived from industry employment, such as stock options distributed as compensation, provided any resulting conflicts were managed appropriately.

Although these provisions were no more onerous than existing financial holdings restrictions that have applied to FDA employees since 1972, the commenters urged the Department to treat NIH employees differently than their counterparts at FDA because the NIH is not primarily a regulatory agency. They also criticized the application of the prohibited holdings rule to all NIH employees regardless of their relative seniority within the organization or the nature of their official duties. Some commented on the focus on substantially affected organizations for all employees rather than on office supplies, computer equipment, and travel-related businesses with which certain employees may have conflicts under pre-existing government-wide rules. A number of commenters asked why the rules applied to spouses and minor children who have no impact on the pharmaceutical and biotechnology

industries, and questioned more generally the exclusion of an entire economic sector from family investment and retirement portfolios.

Many comments demonstrated that the existing law governing conflicts of interest is not well understood. In arguing for elimination of the prohibited holdings rule, a number of commenters assumed incorrectly that a return to the status quo existing prior to the interim final rule invariably would preserve their ability to hold financial interests in substantially affected organizations, without realizing that each employee's situation would still be subject to a case-by-case analysis that could result in a directed divestiture. Others believed incorrectly that potential conflicts can be managed with full disclosure or that no violation can occur as long as the employee's actions do not actually move stock prices. Apparently unaware that those who give advice, conduct research, or recommend action in a government matter can be fully culpable, others saw no need to limit stock holding because they believed erroneously that only decision makers would have financial conflicts. Other commenters criticized a mechanistic or legalistic approach to conflicts without fully comprehending that Federal law prescribes very specific standards.

In implementing those standards, the interim final rule imposed a significantly changed environment for handling potential conflicts of interest arising from financial interests in substantially affected organizations. Congressional oversight and media reports included references to situations in which the connection to industry derived from financial holdings, and not solely from outside consulting. The new rule replaced a case-by-case evaluation of an employee's duties and financial interests with a bright-line rule designed to eliminate financial conflicts altogether. The rule encompassed the holdings of a spouse and minor children because their interests are imputed to the employee under the criminal conflict of interest statute, 18 U.S.C. 208. The changes wrought by the interim final rule were intended to protect both the employee and the agency more effectively.

Regulations governing the conduct of the employees of any agency must reflect the agency's effect on its constituents and stakeholders. The pharmaceutical, biotechnology, and health care industries have changed substantially over the past two decades, and continue to evolve at a rapid pace. The NIH does not exist or work in a vacuum. Every day, the NIH announces findings or results, scientific priorities, or strategic relationships or plans that impact companies in those fields. Any agency that has this power must hold itself and its employees to an appropriate standard. Given the complexity of the financial interests in those industries, monitoring and identifying conflict of interest situations on a case-by-case basis was no longer considered feasible for the NIH.

The interim final rule recognized no difference between ''regulatory'' and ''non-regulatory'' agencies because the legal standards applicable to employee conduct do not make such distinctions. Government agencies, without regard to how their functions may be characterized, exercise significant influence over the activities of non-Federal entities. A core mission of the NIH is to provide the basic science that forms the foundation upon which non-Federal research and development may proceed. Moreover, the potential to affect the financial interests of pharmaceutical and biotechnology companies through clinical trials can be significant. Most importantly, the rule was intended to assure the public in general, and human subjects enrolled in NIH trials in particular, that public health decisions would be made without even the appearance of influence from extraneous financial interests.

Prohibited holdings regulations similar to those applicable to the NIH have been considered an appropriate means to manage potential conflicts and address appearance concerns at various government agencies or agency subcomponents. The prohibitions at those agencies also apply to the financial interests of the employee, spouse, and minor children, and are enforced without regard to the nature of the individual employee's duties. For example, the Department of Housing and Urban Development (HUD) prohibits employee ownership of financial interests in housing and other real estate projects that HUD subsidizes and bars investments in Fannie Mae stock or the securities of other companies that are collateralized by Fannie Mae securities. 5 CFR 7501.104. At the Department of the Treasury, the Office of the Comptroller of the Currency bans investments in the banking industry. 5 CFR 3101.108. Various components of the Environmental Protection Agency (EPA) preclude investments in the automotive, pesticide, and mining industries, and EPA information resources management employees cannot own stock in data management, computer, or information processing firms. 5 CFR 6401.102. At the Department of Transportation, Federal Railroad Administration employees cannot invest in railroads, and Federal Aviation Administration employees are barred from owning stock in an airline or aircraft manufacturing company, or in their suppliers of components or parts. 5 CFR 6001.104.

Against this background, retaining a prohibited holdings regulation at the NIH is amply justified, and comments urging the elimination of the provision have not been adopted. Some commenters recommended retargeting the prohibition toward various subsets of the employee population. These suggestions have received serious consideration, although a number of concerns remain. Retargeting the financial holdings prohibition will require most employees to acquire a more detailed understanding of the law and assume a greater degree of personal responsibility for their actions.

Under the criminal conflict of interest statute, 18 U.S.C. 208, and OGE regulations in 5 CFR parts 2635 and 2640, employees, as well as their spouses and minor children, generally are not able to own stock valued above certain limits if the employees' official duties require them to be involved in particular matters that either involve a company in which they, their spouse, or minor children own stock or that would affect the financial interests of such a company or industry. Absent a waiver under § 208(b), conflicting assets worth more than these limits can be retained only if the employee, without materially impairing his ability to perform the duties of his position, can recuse from working on a matter that would affect the company, and provided that the arrangement does not adversely affect the agency's ability to accomplish its mission.

The task of monitoring investments and recusing appropriately is particularly challenging in an era where mergers, acquisitions, joint ventures, licensing agreements, and corporate name changes are common in the biomedical industry. One of the goals of the prohibited holdings rule was to avoid putting employees into a position where, in a fast paced work environment, they might participate in a government matter at their peril. Further, it had become increasingly difficult to sort through, on a case-by-case basis, these individual circumstances and police such situations to the degree required to maintain public confidence. These concerns remain, but there are other means to attain the desired objective, including increased staffing and resources to address the problem, a massive and continuous effort at

training employees, and holding employees personally accountable for knowing their holdings and recognizing the financial consequences of agency actions in which they may participate. The majority of commenters encouraged the agency to retarget the prohibited holdings rule. Many expressed their belief that stricter enforcement of prior rules would have avoided the problems. They observed that the public perception of the NIH is dependent largely upon the actions of its leadership and of those who are most directly involved in making key decisions that affect human subjects enrolled in clinical trials. A regulatory scheme that insulated senior employees from financial ties to industry was urged as a more measured response to the ethics concerns at the NIH.

The NIH has committed additional staff and resources to ethics program administration. Detailed training development is underway, and a renewed commitment to enforce the rules and to pursue appropriate corrective actions is evident. In this context, the Department has decided to adopt the recommendation that the prohibited holdings rule be limited to senior employees.

For this purpose, ''senior employee'' will include the NIH Director and the NIH Deputy Director; members of the senior staff within the Office of the Director who report directly to the NIH Director; the Directors, the Deputy Directors, Scientific Directors, and Clinical Directors of each NIH institute and center (IC); extramural program officials who report directly to an IC Director; and any employee of equivalent levels of decision-making responsibility who is designated as a senior employee by the designated agency ethics official or the NIH Director, in consultation with the designated agency ethics official.

Senior employees, their spouses, and minor children will be barred from having financial interests in substantially affected organizations, subject to the exceptions for pensions and other employee benefits, diversified mutual funds, and exceptional circumstances that existed under the interim final rule. In addition, because the OGE regulatory exemptions in 5 CFR 2640.201 and 2640.202 allow an employee to participate in certain types of matters depending upon the value of sector mutual fund interests and publicly traded securities within the investment portfolio of the employee, spouse, and minor children, § 5501.110 has been amended to allow senior employees to take advantage of the OGE exemptions. Under current *de minimis* thresholds, and subject to certain limitations, senior employees, their spouses, and minor children will be permitted to retain investments in SAOs capped at $15,000 in any one company. Although they may own multiple $15,000 holdings in SAOs, provided their cumulative interests in SAOs and SAO sector funds are less than 50 percent of their total investments, senior employees will be required, through broker instructions or otherwise, to monitor capital appreciation and divest any portion that exceeds $15,000. Similarly, total investments in sector funds that state in a prospectus the objective or practice of concentrating their investments in the securities of substantially affected organizations will be capped at $50,000. In calculating the fair market value of any holdings, including stock options, that are subject to these exemption limits, guidance issued by OGE for reporting asset values for financial disclosure purposes will apply. Other generally accepted valuation principles, not inconsistent with OGE guidance, also may be utilized.

The $15,000 cap will adjust automatically to any change in the exemption limit for matters involving parties at 5 CFR 2640.202(a), and the $50,000 cap will change in tandem with the sector fund monetary limit at 5 CFR 2640.201(b). As was the case in the interim final rule, although the dollar amounts are linked, an NIH exception and an OGE exemption may not be identical. For example, not all financial interests valued at $15,000 or less will be covered by the OGE regulatory exemption. Although the NIH exception permits a senior employee to hold a financial interest in a non-publicly traded company (assuming all the other criteria in the section are also satisfied), the OGE regulatory exemption only applies to securities in publicly traded companies or long-term Federal Government or municipal securities. Similarly, the NIH exception would permit ownership of stock options valued at $15,000 or less, but the OGE regulatory exemption for interests in securities would not apply. Accordingly, senior employees are reminded that even though § 5501.110 may allow retention of certain assets that would otherwise be prohibited, the financial interest may nevertheless be problematic under 18 U.S.C. 208. Absent a regulatory exemption that specifically addresses the financial interest, a recusal, a divestiture, or an individual waiver may be required.

The exceptional circumstances exception to the prohibited holdings rule, formerly found in paragraph (d)(3) of the interim final rule and now codified in the final rule as paragraph (d)(4), is amended to clarify that an exception may be granted to a class of individuals. Although the prohibition in § 5501.110(c) has been significantly narrowed in its application only to senior employees, their spouses and minor children, class exceptions may be appropriate where the identified class shares a common factual pattern and the requisite reasons for an exception are similarly evident. An example might be an exception for financial interests held by minor children of new entrant senior employees where the minors are within a certain number of months of attaining the age of majority, and the conflict arising from the retention of the financial interests can be managed through appropriate recusals for a time-limited period. Another example might address the inheritance by a senior employee of a prohibited financial interest a few months before retirement.

Section 5501.111 Awards Tendered to Employees of the National Institutes of Health

Section 5501.111, as added by the interim final rule, mandated that a senior NIH employee would not be permitted to accept a gift with an aggregate market value of more than $200, or cash or an investment interest, that constituted an award or incident to an award given because of the employee's official position or from a prohibited source. (Although often referred to as an award, an honor or other recognition that entailed only the receipt of a plaque or other item of little intrinsic value presented at a gathering of interested persons could be accepted if the presentation item satisfied the criteria for exclusion from the gift definition in 5 CFR 2635.203(b), and the free attendance, including food, refreshments, and entertainment, at the event met the exception requirements for widely attended gatherings and other events in 5 CFR 2635.204(g)).

Section 5501.111 prohibited non-senior employees from accepting awards from a person, organization, or other donor that: is seeking official action from the employee, any subordinate of the employee, or any agency component or subcomponent under the employee's official responsibility; does business or seeks to do business with any agency component or subcomponent under the employee's official responsibility; conducts activities substantially affected by any agency component or subcomponent under the employee's official responsibility; or is an organization a majority of whose members fall into one of the above

categories. In other words, such NIH employees could not accept a cash award or one valued at more than $200 that was tendered by a donor that had matters pending under the employee's official responsibility, either individually or before subordinates in the employee's chain of command, irrespective of whether the matter would ever reach the employee for advice or decision.

Upon further consideration, given that the official position and prohibited source criteria for precluding awards to senior employees added little to the official responsibility test applicable to every other employee, section 5501.111 is amended to apply one uniform rule for all employees based on whether the award donor has matters pending under the employee's official responsibility. The section incorporates the definition of ''official responsibility'' contained in 18 U.S.C. 202(b): ''the direct administrative or operating authority, whether intermediate or final, and either exercisable alone or with others, and either personally or through subordinates, to approve, disapprove, or otherwise direct Government action.''

B. Supplemental Financial Disclosure Regulations

5502.105 Agency Procedures

The provision governing reporting procedures is amended to codify the authority of the designated agency ethics official or separate agency components, with the concurrence of the designated agency ethics official, to prescribe standard forms for the collection of information deemed necessary or appropriate to implement part 5502.

5502.106 Supplemental Disclosure of Prohibited Financial Interests Applicable to Employees of the Food and Drug Administration

Section 5502.106, as added by the interim final rule, required FDA and NIH employees to report prohibited financial interests, including those interests that are covered by an applicable exception, within 30 days of joining the agency, being reassigned from another part of HHS, or acquiring such interests, for example, through marriage, gift, or inheritance. This final rule specifies that the value of such interests must be reported. It also removes from § 5502.106 those provisions applicable to NIH employees and places them in a new § 5502.107 in order to correlate with the changes made to the NIH prohibited holdings regulation.

5502.107 Supplemental Disclosure of Financial Interests in Substantially Affected Organizations Applicable to Employees of the National Institutes of Health

New § 5502.107 carries forward the same reporting obligations previously contained in § 5502.106, and clarifies that the value of the reported interests must be disclosed, but revises the class of NIH employees subject to the reporting requirement. With the changes made to 5 CFR 5501.110, subjecting every employee to an extensive and burdensome disclosure obligation is no longer required. Although only senior NIH employees are now subject to a prohibited holdings rule, § 5502.107 will require disclosure of financial interests in substantially affected organizations by filers of public and confidential financial disclosure reports and those employees who are not filers but who serve as clinical investigators designated in an NIH clinical research protocol approved by an institutional review board. The term ''clinical investigator'' means the principal investigator, accountable investigator, lead associate investigator, medical advisory investigator, associate investigators, and other subinvestigators who make direct and significant contributions to the NIH clinical study, and may include registered nurses and allied health professionals so designated. Those employees who file public or confidential financial disclosure reports or who serve as clinical investigators possess budgetary, grant-making, or research authority, exercise discretion at higher levels within the agency, or are in positions with the potential to affect significantly the life and safety of human subjects. Because holdings in substantially affected organizations may continue to pose conflicts for this cohort of employees, and divestiture on a case-by-case basis may be required, disclosure continues to play a critical role in ethics program administration. Accordingly, depending on the number of clinical research protocols approved each year, approximately one-third to one-half of the NIH employee population will remain subject to the disclosure requirement specified in § 5502.107.

New § 5502.107 also restarts the initial reporting date for on-duty employees subject to the revised disclosure rule. Public filers, confidential filers, and clinical investigators on duty at the NIH on the effective date of this final rule must report in writing on or before October 31, 2005, their holdings in substantially affected organizations held on the date the report is filed. Under the prior regulation, the initial report presented a snapshot of an employee's holdings as of the effective date of the rule. As a result of filing extensions, a considerable gap in time could make the information on the filed report out-of-date. Accordingly, under new § 5502.107, the initial disclosure report must be current as of the date of filing.

IV. Matters of Regulatory Procedure

Regulatory Flexibility Act

The Department of Health and Human Services has determined under the Regulatory Flexibility Act, 5 U.S.C. chapter 6, that this rule will not have a significant economic impact on a substantial number of small entities because the rule prescribes personnel provisions that primarily affect HHS employees.

Paperwork Reduction Act

The Paperwork Reduction Act, 44 U.S.C. chapter 35, does not apply to these final rule amendments because they do not contain information collection requirements that are subject to approval by the Office of Management and Budget.

Congressional Review Act

The Department of Health and Human Services has determined that this rulemaking is not a rule as defined in 5 U.S.C. 804, and, thus, does not require review by Congress.

Executive Orders 12866 and 12988

Because this rule relates to HHS personnel, it is exempt from the provisions of Executive Orders 12866 and 12988.

List of Subjects

5 CFR Part 5501

Conflict of interests, Ethics, Executive branch standards of conduct, Financial interests, Government employees, Outside activities.

5 CFR Part 5502

Conflict of interests, Ethics, Government employees, Outside activities, Reporting and recordkeeping requirements.

Dated: August 25, 2005.

Edgar M. Swindell,

Designated Agency Ethics Official, Department of Health and Human Services.

Dated: August 25, 2005.

Michael O. Leavitt,

Secretary, Department of Health and Human Services.

Approved: August 26, 2005.

Marilyn L. Glynn,

General Counsel, Office of Government Ethics.

■ For the reasons discussed in the preamble, the Department of Health and Human Services, with the concurrence of the Office of Government Ethics, adopts as a final rule the interim final rule that amended 5 CFR part 5501 and added 5 CFR part 5502, which was published at 70 FR 5543 on February 3, 2005, and which was amended by the interim final rule published at 70 FR 37009 on June 28, 2005, with the following changes:

Title 5—[Amended]

Chapter XLV—Department of Health and Human Services

PART 5501—SUPPLEMENTAL STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

■ 1. The authority citation for part 5501 continues to read as follows:

Authority: 5 U.S.C. 301, 7301, 7353; 5 U.S.C. App. (Ethics in Government Act of 1978); 25 U.S.C. 450i(f); 42 U.S.C. 216; E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306; 5 CFR 2635.105, 2635.203, 2635.403, 2635.802, 2635.803.

■ 2. Amend § 5501.101 by revising the first sentence of the introductory text in paragraph (c) to read as follows:

§ 5501.101 General.

* * * * *

(c) *Definitions.* Unless a term is otherwise defined in this part, the definitions set forth in 5 CFR parts 2635 and 2640 apply to terms in this part.

* * *

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■ 3. Amend § 5501.102 by revising paragraph (b)(1) to read as follows:

§ 5501.102 Designation of HHS components as separate agencies.

* * * * *

(b) *Definitions*—(1) *Employee of a component* includes, in addition to employees actually within a component, an employee of the Office of the General Counsel whose regularly assigned duties and responsibilities principally involve the provision of legal services to the relevant component with respect to substantive programmatic issues.

* * * * *

■ 4. Amend § 5501.106 as follows:

■ a. Revise paragraph (c)(3)(ii)(B) to read as set forth below;

■ b. Revise paragraphs (d)(1) and (d)(2) to read as set forth below;

■ c. Redesignate paragraphs (d)(3) through (d)(6) as (d)(4) through (d)(7);

■ d. Add new paragraph (d)(3) to read as set forth below;

■ e. Revise redesignated paragraphs (d)(4)(ii)(D) and (d)(4)(ii)(E) to read as set forth below;

■ f. Redesignate paragraphs (d)(4)(ii)(F) through (d)(4)(ii)(N) as (d)(4)(ii)(G) through (d)(4)(ii)(O);

■ g. Revise redesignated paragraphs (d)(4)(ii)(I) through (d)(4)(ii)(K) to read as set forth below;

■ h. Add new paragraph (d)(4)(ii)(F) to read as set forth below;

■ i. Remove the words ''paragraph (d)(3)'' in the second sentence of redesignated paragraph (d)(6) and add, in their place, the words ''paragraph (d)(4)'';

■ j. Revise paragraph (e) to read as set forth below.

The additions and revisions read as follows:

§ 5501.106 Outside employment and other outside activities.

* * * * *

(c) * * *

(3) * * *

(ii) * * *

(B) The employment primarily involves manual or unskilled labor or utilizes talents, skills, or interests in areas unrelated to the substantive programmatic activities of the FDA, such as clerical work, retail sales, service industry jobs, building trades, maintenance, or similar services.

* * * * *

(d) *Prior approval for outside employment and other outside activities*-(1) *General approval requirement.* Except as provided in paragraph (d)(3) of this section, an employee shall obtain written approval prior to engaging, with or without compensation, in outside employment, including self-employed business activities, or other outside activities in which the employee seeks to:

(i) Provide consultative or professional services, including service as an expert witness;

(ii) Engage in teaching, speaking, writing, or editing that:

(A) Relates to the employee's official duties within the meaning of 5 CFR 2635.807(a)(2)(i)(B) through (E); or

(B) Would be undertaken as a result of an invitation to engage in the activity that was extended to the employee by a person or organization that is a prohibited source within the meaning of 5 CFR 2635.203(d), as modified by the separate HHS component agency designations in § 5501.102; or

(iii) Provide services to a non-Federal entity as an officer, director, or board member, or as a member of a group, such as a planning commission, advisory council, editorial board, or scientific or technical advisory board or panel, which requires the provision of advice, counsel, or consultation.

(2) *Additional approval requirement for employees of the Food and Drug Administration and the National Institutes of Health.* In addition to the general approval requirements set forth in paragraph (d)(1) of this section, an employee of the Food and Drug Administration or the National Institutes of Health shall obtain written approval prior to engaging, with or without compensation, in any outside employment, as defined in 5 CFR 2635.603(a), with, or any self-employed business activity involving the sale or promotion of products or services of, any person or organization that is a prohibited source of the employee's component agency.

(3) *Exceptions to prior approval requirements.* (i) Notwithstanding the requirements of paragraphs (d)(1) and (d)(2) of this section, prior approval is not required for participation in the activities of a political, religious, social, fraternal, or recreational organization unless:

(A) The activity or the position held in the organization requires the provision of professional services within the meaning of paragraph (b)(3) of this section; or

(B) The activity is performed for compensation other than the reimbursement of expenses.

(ii) Notwithstanding the requirements of paragraphs (d)(1) and (d)(2) of this section, prior approval is not required for participation in an employment or other outside activity that has been exempted under paragraph (d)(7) of this section.

(4) * * *

(ii) * * *

(D) A description of how the employee's official duties will affect the interests of the person for whom or organization with which the proposed activity will be performed;

(E) The name and address of the person for whom or organization with which the work or activity will be done, including the location where the services will be performed;

(F) A statement as to whether travel is involved and, if so, whether the transportation, lodging, meals, or per diem will be at the employee's expense or provided by the person for whom or organization with which the work or activity will be done, and a description of the arrangements and an estimate of the costs of items to be furnished or reimbursed by the outside entity;

(G) The estimated total time that will be devoted to the activity. If the proposed outside activity is to be performed on a continuing basis, a statement of the estimated number of hours per year; for other employment, a statement of the anticipated beginning and ending date;

(H) A statement as to whether the work can be performed entirely outside of the employee's regular duty hours and, if not, the estimated number of hours and type of leave that will be required;

(I) The method or basis of any compensation to be received (e.g., fee, honorarium, retainer, salary, advance, royalty, stock, stock options, non-travel related expenses, or other form of remuneration tendered in cash or in-kind in connection with the proposed activity) from the person for whom or organization with which the work or activity will be done;

(J) The amount of any compensation to be received from the person for whom or organization with which the work or activity will be done;

(K) The amount and date of any compensation received, or due for services performed, within the current and previous six calendar years immediately preceding the submission of the request for approval from the person for whom or organization with which the work or activity will be done (including any amount received or due from an agent, affiliate, parent, subsidiary, or predecessor of the proposed payor);

(L) A statement as to whether the compensation is derived from an HHS grant, contract, cooperative agreement, or other source of HHS funding or attributed to services related to an activity funded by HHS, regardless of the specific source of the compensation;

(M) For activities involving the provision of consultative or professional services, a statement indicating whether the client, employer, or other person on whose behalf the services are performed is receiving, or intends to seek, an HHS grant, contract, cooperative agreement, or other funding relationship;

(N) For activities involving teaching, speaking, or writing, a syllabus, outline, summary, synopsis, draft or similar description of the content and subject matter involved in the course, speech, or written product (including, if available, a copy of the text of any speech) and the proposed text of any disclaimer required by 5 CFR 2635.807(b)(2) or by the instructions or manual issuances authorized under paragraph (d)(7) of this section; and

(O) Such other relevant information that the designated agency ethics official or, with the concurrence of the designated agency ethics official, each of the separate agency components of HHS listed in § 5501.102(a) determines is necessary or appropriate in order to evaluate whether a proposed activity is likely to involve conduct prohibited by statute or Federal regulations, including 5 CFR part 2635 and this part.

* * * * *

(6) *Duration of approval.* Approval shall be effective for a period not to exceed one year from the date of approval. Upon a significant change in the nature of the outside activity or in the employee's official position or duties, the employee shall submit a revised request for approval using the procedure in paragraph (d)(4) of this section. * * *

* * * * *

(e) *Waivers.* The designated agency ethics official may grant a written waiver, for an individual or class of similarly situated individuals, from any prohibited outside activity provision in this section or in § 5501.109 based on a determination that the waiver is not inconsistent with part 2635 of this title or otherwise prohibited by law and that, under the particular circumstances, application of the prohibition is not necessary to avoid the appearance of misuse of position or loss of impartiality or otherwise to ensure confidence in the impartiality and objectivity with which agency programs are administered. An individual or class waiver under this paragraph may impose appropriate conditions, such as requiring execution of a written disqualification.

■ 5. Amend § 5501.109 as follows:
■ a. Remove paragraph (b)(6);
■ b. Redesignate paragraphs (b)(7) through (b)(11) as (b)(9) through (b)(13);
■ c. Redesignate paragraph (b)(5) as (b)(8);
■ d. Add new paragraphs (b)(6) and (b)(7) to read as set forth below;
■ e. Redesignate paragraphs (b)(3) and (b)(4) as (b)(4) and (b)(5);
■ f. Add new paragraph (b)(3) to read as set forth below;
■ g. Revise redesignated paragraphs (b)(4), (b)(8), (b)(10), (b)(11), and (b)(13) introductory text to read as set forth below;
■ h. Revise paragraph (c)(1) to read as set forth below;
■ i. Revise paragraphs (c)(3)(i), (c)(3)(iii) and (c)(3)(v) to read as set forth below;
■ j. Add new paragraphs (c)(3)(vi) through (c)(3)(viii) to read as set forth below;
■ k. Remove paragraphs (c)(4) and (c)(5).

The additions and revisions read as follows:

§ 5501.109 Prohibited outside activities applicable to employees of the National Institutes of Health.

* * * * *

(b) * * *

(3) *Data and safety monitoring board* (DSMB) means a board, committee, or panel constituted in connection with an ongoing clinical study and comprised of individuals, other than the study sponsors, organizers, and investigators, who possess expertise in relevant specialties and disciplines, such as trial design, biostatistics, and bioethics, and who review accumulating safety and outcome data in order to ensure the continuing safety of the participating human subjects and of those yet to be recruited, and to assess the continuing validity and scientific merit of the investigation.

(4) *Educational activity provider* means a supported research institution or a health care provider or insurer that presents Grand Rounds or offers accredited continuing professional education (or, in the case of a profession or academic discipline whose members are not subject to licensure and which does not have program accreditation requirements, an education program determined by the designated agency ethics official or his designee or, in consultation with the designated agency ethics official or his designee, the NIH Director or the NIH Director's designee to be substantially equivalent to an accredited continuing professional education program), but does not include a substantially affected organization.

(5) *Employment* has the meaning specified in 5 CFR 2635.603(a).

(6) *Grand Rounds* means a regularly scheduled, interactive presentation or series of educational seminars that focus on clinical cases, recent biomedical or behavioral research results, or a review of scientific research methods and findings in a specific field, with supporting basic and clinical science information, that are conducted in an accredited medical school or an affiliated teaching hospital setting that provides practicing physicians, faculty, fellows, resident physician trainees, medical students, graduate students, and post-doctoral fellows, as well as allied and associated health professionals, and other staff, an

opportunity to evaluate outcomes of patient treatment decisions, a forum to discuss clinical decision making, and a means to impart updates in diagnosis, treatment, therapy, and research as indicated by the context of the cases presented.

(7) *Grant or scientific review committee* means a board, committee, or panel of qualified experts assembled by an external grant-making entity or other funding institution for the purpose of making a funding decision, the members of which review, evaluate, rate, rank, or otherwise assess a proposed or ongoing project or program for which grant support is sought on the basis of various factors, such as scientific merit, feasibility, significance, approach, and originality (and scientific progress in any previous period of funding), and gauge the ability of the applicant(s), principal and associate investigators, and scientific team members to complete successfully the project or program, and then recommend to the grantor whether to fund or continue to fund a particular proposal or ongoing program.

(8) *Health care provider or insurer* means a hospital, clinic, skilled nursing facility, rehabilitation facility, durable medical equipment supplier, home health agency, hospice program, health maintenance organization, managed care organization, or other provider of health care items and services as defined in sections 1877(h)(6) or 1903(w)(7) of the Social Security Act (42 U.S.C. 1395nn(h)(6) or 1396b(w)(7)) and any entity organized and licensed as a risk-bearing entity eligible to offer health insurance or health benefits coverage.

(9) *Scientific peer review* is the evaluation of scientific research findings for competence, significance, and originality by qualified experts who research and submit work for publication in the same field and which provides systematized accountability for adherence to ethical guidelines commonly accepted within the relevant research community for disseminating scientific information.

(10) *Substantially affected organization* means:

(i) A biotechnology or pharmaceutical company; a medical device manufacturer; or a corporation, partnership, or other enterprise or entity significantly involved, directly or through subsidiaries, in the research, development, or manufacture of biotechnological, biostatistical, pharmaceutical, or medical devices, equipment, preparations, treatments, or products;

(ii) Any organization a majority of whose members are described in paragraph (b)(10)(i) of this section; and

(iii) Any other organization determined by the designated agency ethics official or, in consultation with the designated agency ethics official, by the NIH Director or the NIH Director's designee that is substantially affected by the programs, policies, or operations of the NIH.

(11) *Supported research institution* means any educational institution or non-profit independent research institute that:

(i) Is, or within the last year has been, an applicant for or recipient of an NIH grant, cooperative agreement, or research and development contract;

(ii) Is, or within the last year has been, a proposer of or party to a cooperative research and development agreement (CRADA) with the NIH; or

(iii) Any organization a majority of whose members are described in paragraphs (b)(11)(i) or (ii) of this section.

(12) *Unrestricted educational grant* means funds received by or available to an educational activity provider from another source that are granted without stipulated conditions for their use other than the limitation that the funds shall be used to advance an educational program of the grant recipient. For purposes of this section, an educational grant shall not be considered unrestricted if the funding source for a Grand Rounds or a continuing professional education program directly or indirectly:

(i) Selects or recommends the moderators, speakers, or presenters at the sponsored event;

(ii) Independently provides additional funding to the moderators, speakers, or presenters in connection with the educational activity;

(iii) Determines or recommends the audience composition;

(iv) Specifies or recommends the topics to be addressed, or

(v) Controls or recommends the planning, content, or implementation of the program in a manner inconsistent with guidelines established by a relevant professional association or accrediting organization that are designed to ensure that such activities are accurate, balanced, educational, free from commercial bias, nonpromotional, and independent of the influence of the funding source.

(13) *Unrestricted financial contribution* means funds received by or available to a publisher, academic press, editorial board, or other entity affiliated with or operated by a supported research institution or a health care provider or insurer from another source that are provided without stipulated conditions for their use other than the limitation that the funds shall be used to advance peer-reviewed writing or editing by the funds recipient. For purposes of this section, a financial contribution shall not be considered unrestricted if the funding source for peer-reviewed writing or editing directly or indirectly: * * *

* * * * *

(c) *Prohibitions*—(1) *Prohibited outside activities with substantially affected organizations, supported research institutions, and health care providers or insurers.* Except as permitted by paragraph (c)(3) of this section, an employee of the NIH shall not:

(i) Engage in employment with a substantially affected organization, a supported research institution, or a health care provider or insurer;

(ii) Teach, speak, write, or edit for compensation for any substantially affected organization, supported research institution, or health care provider or insurer; or

(iii) Engage in any employment or self-employed business activity that involves the sale or promotion of products or services of a substantially affected organization or a health care provider or insurer, except for the purpose of commercializing invention rights obtained by the employee pursuant to Executive Order 10096, 15 U.S.C. 3710d, or implementing regulations.

* * * * *

(3) * * *

(i) *Teaching.* An employee may engage in and accept compensation for:

(A) Teaching a course requiring multiple presentations as permitted under 5 CFR 2635.807(a)(3); or

(B) Delivering a class lecture that is unrelated to the employee's official duties within the meaning of 5 CFR 2635.807 if the activity is performed as part of a regularly scheduled course offered under the established curriculum of an institution of higher education as defined at 20 U.S.C. 1001.

* * * * *

(iii) *Clerical, retail, service industry, building trades, maintenance, or similar services.* An employee may engage in and accept compensation for any outside employment or self-employed business activity that primarily involves manual or unskilled labor or utilizes talents, skills, or interests in areas unrelated to the health and scientific research activities of the NIH, such as clerical work, retail sales, service

industry jobs, building trades, maintenance, or similar services.

* * * * *

(v) *Authorship of writings subjected to scientific peer review or a substantially equivalent editorial review process.* An employee may engage in and accept compensation for a writing or editing activity that is unrelated to the employee's official duties within the meaning of 5 CFR 2635.807 if the resulting article, chapter, essay, report, text, or other writing is submitted to a publisher, academic press, editorial board, or other entity affiliated with or operated by a supported research institution or a health care provider or insurer for publication in a scientific journal, textbook, or similar publication that subjects manuscripts to scientific peer review or a substantially equivalent editorial review process. If a substantially affected organization funds the publishing activities of a supported research institution or a health care provider or insurer, this exception is inapplicable unless the substantially affected organization is involved only as an unrestricted financial contributor and exercises no editorial control.

(vi) *Data and safety monitoring boards.* An employee may serve as a member of a data and safety monitoring board for a clinical study conducted by a supported research institution or health care provider or insurer, provided that:

(A) The members of the DSMB are not selected or paid for their service by a substantially affected organization;

(B) The clinical study is not funded under a grant, cooperative agreement, or research and development contract from, or conducted pursuant to a cooperative research and development agreement (CRADA) with, or aided under another funding mechanism by, the NIH; and

(C) If the service is performed for compensation, the service does not entail prohibited assistance in the preparation of documents intended for submission to HHS within the meaning of § 5501.106(c)(1), and the clinical study is not an HHS-funded activity described in § 5501.106(c)(2).

(vii) *Grand Rounds.* An employee may engage in and accept compensation for a teaching, speaking, writing, or editing activity that is unrelated to the employee's official duties within the meaning of 5 CFR 2635.807 if the activity is performed as part of a Grand Rounds program conducted by an accredited educational institution offering instruction in the life sciences, such as a medical school or school of public health, or by an affiliated teaching hospital, provided that:

(A) The employee's presentation includes an interactive component, such as visiting patients or discussing individual clinical cases, or interacting for educational purposes with undergraduates, graduates, or post-graduate students and fellows, in addition to any lecture;

(B) The audience is composed primarily of faculty and students or trainees registered in a biomedical or health-related program of studies; and

(C) A substantially affected organization or a speakers' bureau affiliated with a substantially affected organization does not sponsor or underwrite the costs of the Grand Rounds program or the employee's presentation, except pursuant to an unrestricted educational grant.

(viii) *Grant or scientific review committee.* An employee may serve on a grant or scientific review committee for a supported research institution or a health care provider or insurer, provided that:

(A) The members of the grant or scientific review committee are not selected or paid for their service by a substantially affected organization;

(B) The grant award or program in relation to which the recommendation of the grant or scientific review committee is sought is not funded under a grant, cooperative agreement, or research and development contract from, conducted pursuant to a cooperative research and development agreement (CRADA) with, or aided under another funding mechanism by, the NIH; and

(C) If the service is performed for compensation, the service does not entail prohibited assistance in the preparation of documents intended for submission to HHS within the meaning of § 5501.106(c)(1), and the grant award or program in relation to which the recommendation of the grant or scientific review committee is sought is not an HHS-funded activity described in § 5501.106(c)(2).

■ 6. Amend § 5501.110 as follows:

■ a. Revise the section heading to read as set forth below;

■ b. Remove paragraphs (b)(1), (b)(2), and (b)(4);

■ c. Redesignate paragraph (b)(3) as (b)(2);

■ d. Revise redesignated paragraph (b)(2) to read as set forth below;

■ e. Add new paragraph (b)(1) to read as set forth below;

■ f. Remove paragraphs (c), (d), (e), and (f) and the notes to paragraphs (e)(1) and (e);

■ g. Redesignate paragraph (g) as (e) and revise redesignated paragraph (e) to read as set forth below;

■ h. Add new paragraphs (c) and (d) and notes to paragraphs (d)(1) and (d) to read as set forth below.

The additions and revisions read as follows:

§ 5501.110 Prohibited financial interests applicable to senior employees of the National Institutes of Health.

* * * * *

(b) * * *

(1) *Senior employee* means the Director and the Deputy Director of the National Institutes of Health; members of the senior staff within the Office of the Director who report directly to the NIH Director; the Directors, the Deputy Directors, Scientific Directors, and Clinical Directors of each Institute and Center within NIH; Extramural Program Officials who report directly to an Institute or Center Director; and any employee of equivalent levels of decision-making responsibility who is designated as a senior employee by the designated agency ethics official or the NIH Director, in consultation with the designated agency ethics official.

(2) *Substantially affected organization* has the meaning set forth in § 5501.109(b)(10).

(c) *Prohibition applicable to senior employees.* Except as permitted by paragraph (d) of this section, a senior employee or the spouse or minor child of such senior employee shall not have a financial interest in a substantially affected organization.

(d) *Exceptions for certain financial interests.* Notwithstanding the prohibition in paragraph (c) of this section:

(1) *Pension or other employee benefit.* A senior employee or spouse or minor child of a senior employee may have a financial interest, such as a pension or other employee benefit, arising from employment with a substantially affected organization.

Note to Paragraph (d)(1): NIH employees, as opposed to spouses and minor children of employees, are generally prohibited under § 5501.109 from engaging in current employment with a substantially affected organization.

(2) *De minimis holdings.* A senior employee or spouse or minor child of a senior employee may have a financial interest in a substantially affected organization if:

(i) The aggregate market value of the combined interests of the senior employee and the senior employee's spouse and minor children in any one substantially affected organization is equal to or less than the *de minimis* exemption limit for matters involving parties established by 5 CFR 2640.202(a) or $15,000, whichever is greater;

(ii) The holding, if it represents an equity interest, constitutes less than 1 percent of the total outstanding equity of the organization; and

(iii) The total holdings in substantially affected organizations and sector mutual funds that, in the literature they distribute to prospective and current investors or participants, state the objective or practice of concentrating their investments in the securities of substantially affected organizations account for less than 50 percent of the total value of the combined investment portfolios of the senior employee and the senior employee's spouse and minor children.

(3) *Diversified mutual funds.* A senior employee or spouse or minor child of a senior employee may have an interest in a substantially affected organization that constitutes any interest in a publicly traded or publicly available investment fund (*e.g.*, a mutual fund), or a widely held pension or similar fund, which, in the literature it distributes to prospective and current investors or participants, does not indicate the objective or practice of concentrating its investments in substantially affected organizations, if the employee neither exercises control nor has the ability to exercise control over the financial interests held in the fund.

(4) *Exceptional circumstances.* In cases involving exceptional circumstances, the NIH Director or the NIH Director's designee, with the approval of the designated agency ethics official or his designee, may grant a written exception to permit a senior employee, or the spouse or minor child of a senior employee, or a class of such individuals, to hold a financial interest in a substantially affected organization based upon a determination that the application of the prohibition in paragraph (c) of this section is not necessary to ensure public confidence in the impartiality or objectivity with which HHS programs are administered or to avoid a violation of part 2635 of this title.

(5) *Technology transfer.* A senior employee may have a financial interest in connection with the development and commercialization of invention rights obtained by the employee pursuant to Executive Order 10096, 15 U.S.C. 3710d, or implementing regulations.

(6) *Sector mutual funds.* (i) A senior employee or spouse or minor child of a senior employee may have an interest in a substantially affected organization that constitutes any interest in a sector mutual fund that, in the literature it distributes to prospective and current investors or participants, does not indicate the objective or practice of concentrating its investments in the biomedical science, pharmaceutical, medical device, biotechnology, or health industry sectors.

(ii) A senior employee or spouse or minor child of a senior employee may have an interest in a substantially affected organization that constitutes any interest in a sector mutual fund that, in the literature it distributes to prospective and current investors or participants, states the objective or practice of concentrating its investments in the securities of substantially affected organizations provided that:

(A) The aggregate market value of the combined ownership interests of the senior employee and the senior employee's spouse and minor children in such sector funds is equal to or less than the *de minimis* exemption limit for sector mutual funds established by 5 CFR 2640.201(b)(2)(i) or $50,000, whichever is greater; and

(B) The total holdings in substantially affected organizations and in sector mutual funds that, in the literature they distribute to prospective and current investors or participants, state the objective or practice of concentrating their investments in the securities of substantially affected organizations account for less than 50 percent of the total value of the combined investment portfolios of the senior employee and the senior employee's spouse and minor children.

Note to Paragraph (d): With respect to any excepted financial interest, employees are reminded of their obligations under 5 CFR part 2635, and specifically their obligation under subpart D to disqualify themselves from participating in any particular matter in which they, their spouses or minor children have a financial interest arising from publicly traded securities that exceeds the *de minimis* thresholds specified in the regulatory exemption at 5 CFR 2640.202 or from non-publicly traded securities that are not covered by the regulatory exemption. Furthermore, the agency may prohibit or restrict an individual employee from acquiring or holding any financial interest or a class of financial interests based on the agency's determination that the interest creates a substantial conflict with the employee's duties, within the meaning of 5 CFR 2635.403.

(e) *Reporting and divestiture.* For purposes of determining the divestiture period specified in 5 CFR 2635.403(d), as applied to financial interests prohibited under paragraph (c) of this section, the ''date divestiture is first directed'' means the date on which the new entrant public or confidential financial disclosure report required by part 2634 of this title or any report required by § 5502.107(c) of this chapter is due.

■ 7. Amend § 5501.111 as follows:
■ a. Redesignate paragraphs (b), (c), and (d) as (c), (d) and (e);
■ b. Redesignate the note to paragraph (b) as the note to paragraph (c);
■ c. Add new paragraph (b) to read as set forth below;
■ d. Remove redesignated paragraph (c)(1) and redesignate paragraphs (c)(2) and (c)(3) as (c)(1) and (c)(2);
■ e. In the introductory text of redesignated paragraph (c)(1), remove the phrase ''other than a senior employee'';
■ f. Revise redesignated paragraph (c)(1)(iv) to read as set forth below;
■ g. Revise the introductory text of redesignated paragraph (d) to read as set forth below;
■ h. Revise redesignated paragraphs (d)(2) and (d)(3) to read as set forth below;
■ i. Revise redesignated paragraph (e)(1) and the introductory text of redesignated paragraph (e)(2) to read as set forth below.

The additions and revisions read as follows:

§ 5501.111 Awards tendered to employees of the National Institutes of Health.

* * * * *

(b) *Definitions.* For purposes of this section, official responsibility has the meaning set forth in 18 U.S.C. 202(b).

(c) *Additional limitations on awards to employees of the National Institutes of Health.* The following limitations shall apply to the acceptance by an employee of an award pursuant to 5 CFR 2635.204(d):

(1) *Limitations applicable to employees with official responsibility for matters affecting an award donor.* An employee shall not accept a gift with an aggregate market value of more than $200, or that is cash or an investment interest, that is an award or incident to an award from a person, organization, or other donor that:

* * * * *

(iv) Is an organization a majority of whose members are described in paragraphs (c)(1)(i) through (iii) of this section.

(2) *Prior approval of awards.* (i) No employee shall accept an award under 5 CFR 2635.204(d) or this section unless the receipt thereof has been approved in writing in advance in accordance with procedures specified by the designated agency ethics official, or with the concurrence of the designated agency ethics official, the NIH Director or the NIH Director's designee.

(ii) Approval shall be granted only upon a determination that acceptance of

the award is not prohibited by statute or Federal regulation, including 5 CFR part 2635 and this part.

Note to Paragraph (c): In some circumstances cash and other things of value provided in connection with the provision of personal services, including speaking or writing, may be compensation, not a gift. Other ethics rules governing outside activities may restrict receipt of such compensation. See, for example, 5 CFR 2635.807.

(d) *Exception.* Notwithstanding the prohibition in paragraph (c)(1) of this section, the NIH Director (or the Secretary, with respect to awards tendered to the NIH Director), with the approval of the designated agency ethics official, may grant a written exception to permit an employee to accept an award otherwise prohibited by this section under the following conditions:

* * * * *

(2) Absent the prohibition in paragraph (c)(1) of this section, the gift would be permitted under part 2635 of this title; and

(3) The designated agency ethics official shall have determined that the application of the prohibition in paragraph (c)(1) of this section is not necessary to ensure public confidence in the impartiality or objectivity with which NIH programs are administered or to avoid a violation of part 2635 of this title.

(e) *Disposition of improperly accepted awards.*—(1) *Failure to obtain prior approval.* If an employee accepts an award for which approval is required under paragraph (c)(2) of this section without obtaining such approval, the employee may be required, in addition to any penalty provided by law and applicable regulations, to forfeit the award by returning it to the donor.

(2) *Receipt of prohibited award.* If an employee accepts an award prohibited by paragraph (c)(1) of this section, the employee shall be required, in addition to any penalty provided by law and applicable regulations, to:

* * * * *

PART 5502—SUPPLEMENTAL FINANCIAL DISCLOSURE REQUIREMENTS FOR EMPLOYEES OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

■ 8. The authority citation for part 5502 continues to read as follows:

Authority: 5 U.S.C. 301, 7301; 5 U.S.C. App. (Ethics in Government Act of 1978); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306; 5 CFR 2634.103.

§ 5502.102 [Amended]

■ 9. Amend § 5502.102 by removing from the second sentence the citation to ''§ 5501.106(d)(4)'' and add in its place the citation ''§ 5501.106(d)(5)''.

■ 10. Amend § 5502.105 by revising paragraph (a) to read as follows:

§ 5502.105 Agency procedures.

(a) The designated agency ethics official or, with the concurrence of the designated agency ethics official, each of the separate agency components of HHS listed in § 5501.102(a) of this chapter may prescribe forms for the collection of information under this part and establish procedures for the submission and review of each report filed. These procedures may provide for filing extensions, for good cause shown, totaling not more than 90 days.

* * * * *

■ 11. Amend § 5502.106 by revising the section heading and paragraphs (b)(2) and (c) to read as follows:

§ 5502.106 Supplemental disclosure of prohibited financial interests applicable to employees of the Food and Drug Administration.

* * * * *

(b) * * *

(2) *Prohibited financial interest* means a financial interest prohibited by § 5501.104(a), including those financial interests that are excepted under § 5501.104(b) of this chapter.

* * * * *

(c) *Report of prohibited financial interests.*—(1) *New entrant employees.* A new entrant employee, other than a public filer or a confidential filer, shall report in writing within 30 days after entering on duty with the FDA any prohibited financial interest and the value thereof held upon commencement of employment with the agency.

(2) *Reassigned employees.* An employee of a separate agency component other than the FDA or of the remainder of HHS who is reassigned to a position at the FDA shall report in writing within 30 days of entering on duty with the FDA any prohibited financial interest and the value thereof held on the effective date of the reassignment to the agency.

(3) *Incumbent employees.* An incumbent employee of the FDA who acquires any prohibited financial interest shall report such interest and the value thereof in writing within 30 days after acquiring the financial interest.

■ 12. Add new § 5502.107 to read as follows:

§ 5502.107 Supplemental disclosure of financial interests in substantially affected organizations applicable to employees of the National Institutes of Health.

(a) *Applicability.* This section does not apply to special Government employees.

(b) *Definitions.* For purposes of this section:

(1) *Clinical investigator* means an employee identified as a principal investigator, accountable investigator, lead associate investigator, medical advisory investigator, associate investigator, or other subinvestigator in an NIH clinical study involving human subjects under a clinical research protocol approved by an institutional review board.

(2) *Clinical research* has the meaning set forth in 42 U.S.C. 284d(b).

(3) *Institutional review board* (IRB) means any board, committee, or other group formally designated by an institution to review a clinical research protocol and approve the initiation of biomedical research involving human subjects and to assess periodically the progress of the investigation to protect the rights and welfare of the trial participants.

(4) *Confidential filer* means an employee who meets the criteria in 5 CFR 2634.904 and who has not been excluded from the requirement of filing a confidential financial disclosure report under the procedures in 5 CFR 2634.905.

(5) *Public filer* means an employee who meets the criteria in 5 CFR 2634.202 and who has not been excluded from the requirement of filing a public financial disclosure report under the procedures in 5 CFR 2634.203.

(6) *Remainder of HHS* has the meaning set forth in § 5501.102(b)(2) of this chapter.

(7) *Separate agency component* has the meaning set forth in § 5501.102(a) of this chapter.

(8) *Substantially affected organization* has the meaning set forth in § 5501.109(b)(10) of this chapter.

(c) *Report of financial interests in substantially affected organizations.*—(1) *New entrant employees.* A new entrant employee, other than a public filer or a confidential filer, who is designated to serve as a clinical investigator shall report in writing within 30 days after entering on duty with the NIH any financial interest in a substantially affected organization and the value thereof held upon commencement of employment with the agency.

(2) *Reassigned employees.* An employee of a separate agency

component, other than the NIH, or of the remainder of HHS who is either a public filer, a confidential filer, or a clinical investigator who is reassigned to a position at the NIH shall report in writing within 30 days of entering on duty with the NIH any financial interest in a substantially affected organization and the value thereof held on the effective date of the reassignment to the agency.

(3) *Incumbent employees.* An incumbent employee of the NIH who is either a public filer, a confidential filer, or a clinical investigator who acquires any financial interest in a substantially affected organization shall report such interest and the value thereof in writing within 30 days after acquiring the financial interest. Any incumbent employee, irrespective of financial disclosure filing status, who is designated a clinical investigator shall report in writing within 30 days of the approval of the clinical research protocol by the relevant institutional review board any financial interest in a substantially affected organization and the value thereof held on the date of the IRB approval.

(4) *Initial report by on duty employees.* An employee on duty at the NIH on August 31, 2005, who is either a public filer, a confidential filer, or a clinical investigator shall report in writing on or before October 31, 2005, any financial interest in a substantially affected organization and the value thereof held on the date the report is filed.

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 906

[Docket No. FV05–906–1 IFR]

Oranges and Grapefruit Grown in Lower Rio Grande Valley in Texas; Changes to Container and Pack Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim final rule with request for comments.

SUMMARY: This rule revises the container and pack requirements currently prescribed under the marketing order (order) covering oranges and grapefruit grown in the Lower Rio Grande Valley in Texas. The order regulates the handling of such fruit and is administered locally by the Texas Valley Citrus Committee (Committee). This rule revises the orange and grapefruit rules and regulations and container requirements by adding eight new containers to the list of authorized containers for use by Texas citrus handlers, removing one obsolete container, and by combining all the requirements on authorized bags into one grouping for easier reference. Other changes would revise incorrect references to the U.S. grade standards for oranges and grapefruit grown in Texas. These changes are expected to help handlers compete more effectively in the marketplace, better meet the needs of buyers, and to improve producer returns.

DATES: Effective September 1, 2005; comments received by October 31, 2005 will be considered prior to issuance of a final rule.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule. Comments must be sent to the Docket Clerk, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; E-mail: *moab.docketclerk@usda.gov;* or Internet: *http://www.regulations.gov.* All comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be made available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *http://www.ams.usda.gov/fv/moab.html.*

FOR FURTHER INFORMATION CONTACT: Belinda G. Garza, Regional Manager, Texas Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA; Telephone: (956) 682–2833, Fax: (956) 682–5942; or George Kelhart, Technical Advisor, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938.

Small businesses may request information on complying with this regulation by contacting Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or E-mail: *Jay.Guerber@usda.gov.*

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Agreement and Order No. 906, as amended (7 CFR part 906), regulating the handling of oranges and grapefruit grown in the Lower Rio Grande Valley in Texas, hereinafter referred to as the ''order.'' The marketing agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Order 12866.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This rule revises container and pack requirements currently prescribed under the Texas orange and grapefruit order and makes several conforming and formatting changes. The rule revises the rules and regulations and container requirements by adding eight new containers to the list of authorized containers for use by Texas citrus handlers, removing one obsolete container, combining all of the requirements on authorized bags into one grouping for easier reference. Other changes include revising incorrect references to the U.S. grade standards for oranges and grapefruit grown in Texas and States other than Florida, California, and Arizona (7 CFR 51.680 through 51.714 for oranges, and 7 CFR 51.620 through 51.653 for grapefruit). See 68 FR 46433, August 6, 2003; and 66 FR 48785, September 24, 2001, for information on changes in the grade standards that necessitate changes to the Texas citrus handling regulations.