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| REGULATION CERTIFICATION FOR SPECIAL GOVERNMENT EMPLOYEES | NAME OF EMPLOYEE <i>(Type or print)</i> | SOCIAL SECURITY NO. |
| | CENTER/OFFICE | |

I. INFORMATION CONCERNING PROTECTION OF CONFIDENTIAL DATA

The public interest requires that certain information in the possession of the Government be kept confidential and released only with general or specific authority under Department or operating agency regulations. This is necessary because it may involve national security or because it is private, personal, or business information which has been furnished to the Government in confidence. The following paragraphs set forth the rules to be followed by FDA employees in handling information in official files or documents.

- (a) The Food and Drug Administration obtains in the course of its program activities certain information from businesses or individuals which it is forbidden by law from disclosing. This statutory prohibition [21 U.S.C. 331(j)] states: "The following acts and the causing thereof are hereby prohibited: The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Chapter, any information acquired under authority of section 344, 348, 350a, 355, 360, 360b, 360c, 360d, 360e, 360f, 360h, 360i, 360j, 374, 379, or 379e, of this title concerning any method or process which as a trade secret is entitled to protection." Each employee is responsible for observing this law. In addition, the Trade Secret Act provides criminal penalties for unauthorized disclosure of trade secrets and confidential commercial or financial information.
- (b) Government employees are sometimes able to obtain information about some action the Government is about to take or some other matter which is not generally known. Information of this kind shall not be used by the employee to further his/her or someone else's private financial or other interests. Such use of official information is clearly a violation of the Standards of Ethical Conduct for Employees of the Executive Branch, 5 CFR para. 2635.703. Employees shall not, directly or indirectly, make use of, or permit others to make use of, for the purpose of furthering a private interest, official information not made available to the general public.

II. CONFLICT OF INTEREST STATUTES

Each employee should acquaint himself or herself with sections 203, 205 and 208 of Title 18, United States Code, all of which carry criminal penalties related to conflicts of interest.

- (a) Section 205 precludes special Government employees from acting as agent or attorney (1) in a matter involving specific parties in which he/she has participated personally and substantially in his/her Government capacity, and (2) in a matter involving a specific party or parties which is before his/her department or agency [DHHS], if he/she has served therein more than 60 days in the past year.
- (b) Section 203 precludes special Government employees from receiving compensation for any representational services, whether rendered personally or by someone else, (1) in a matter involving specific parties in which he/she has participated personally and substantially in his/her government capacity, and (2) in a matter involving a specific party or parties which is before his/her department or agency [DHHS], if he/she has served therein more than 60 days in the past year.
- (c) Section 208 precludes a special Government employee from participating personally and substantially in a particular matter which, to his/her knowledge, has a direct and predictable effect on a financial interest of any of the following: the employee, the employee's spouse or minor child, the employee's general partner, any organization which the employee serves as officer, director, trustee, general partner or employee, or any organization with whom the employee is negotiating or has any arrangement concerning prospective employment.

III. RULES CONCERNING SEPARATED GOVERNMENT EMPLOYEES

Your attention is directed to the following statutory prohibition for special Government employees who leave the employment of the U.S. Government (18 U.S.C. 207):

After leaving Government, a former special Government employee is permanently prohibited from making any communication or appearance on behalf of any other person before the Government, with the intent to influence the Government in connection with any matter involving specific parties in which the former employee participated personally and substantially for the Government. (Special Government employees who serve 60 days or more in the one year period before leaving Government may be subject to additional restrictions, depending on their pay level.)

IV. CERTIFICATION

I certify that:

- (a) I understand the above cited requirements for use of official information and the provisions applicable to conflict of interest including 18 U.S.C. 207 which applies after I separate from the Federal Service, and
- (b) I have received a copy of the Government wide Standards of Ethical Conduct and the DHHS Supplemental Standards of Ethical Conduct, and understand that I am personally responsible for complying with these provisions.

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| SIGNATURE | DATE |
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