DEPARTMENT OF HEALTH AND HUMAN SERVICES

REPORT OF PROHIBITED FINANCIAL INTERESTS FOR EMPLOYEES OF THE FOOD AND DRUG ADMINISTRATION

(HHS Supplemental Ethics Regulation 5 CFR 5501.104
HHS Supplemental Financial Disclosure Regulation 5 CFR 5502.106)

☐ New Entrant ☐ Reassignment ☐ Incumbent	DATE ENTERED ON DUTY OR REASSIGNED	DATE REPORT FILED

I. EMPLOYEE INFORMATION

1. EMPLOYEE'S NAME *(Last, First, MI)*

2. AGENCY *(Office/Center)*	COMPONENT	
3. TITLE OF POSITION	4. GRADE/STEP	5. FEDERAL SALARY

6. APPOINTMENT TYPE

☐ PAS/PA ☐ Non-Career SES ☐ Career SES ☐ Schedule C ☐ Commissioned Corps

☐ General Schedule ☐ Title 42 ☐ Other _____

7. FINANCIAL DISCLOSURE FILING STATUS

☐ Public *(SF 278)*

☐ Confidential *(OGE 450)* ☐ None

8. OFFICE ADDRESS *(Street)*

CITY	STATE	ZIP

9. OFFICE CONTACT INFORMATION

TELEPHONE	FAX
( )	( )
CELL	EMAIL
( )	

10. NAME OF IMMEDIATE SUPERVISOR	11. TITLE OF SUPERVISOR

12. SUPERVISOR CONTACT INFORMATION

TELEPHONE	FAX
( )	( )
CELL	EMAIL
( )	

AGENCY USE ONLY

II. PROHIBITED FINANCIAL INTERESTS

If none, check this box. ☐ None

1. Report

For you, your spouse, and minor children, report all financial interests, such as stocks, bonds, stock options, and other investments or ownership interests, in **significantly regulated organizations** that you held as of the date you entered on duty with or were reassigned to the FDA. If you are a current employee, you should use this form to report any financial interests in significantly regulated organizations that you acquired after your initial appointment, such as through marriage, gift, or inheritance. The term "significantly regulated organization" means an organization for which the sales of products regulated by the FDA constitute ten percent or more of annual gross sales in the organization's previous fiscal year; where an organization does not have a record of sales of FDA-regulated products, it will be deemed to be significantly regulated if its operations are predominately in fields regulated by FDA, or if its research, development, or other business activities are reasonably expected to result in the development of products that are regulated by FDA.

Consult the FDA Ethics and Integrity Staff (EIS) for assistance in identifying companies in the **food, beverage, cosmetics, biotechnology, pharmaceutical, medical device, and related industries and** any other organizations that are significantly regulated. A listing of significantly regulated organizations can be found at http://www.fda.gov/AboutFDA/WorkingatFDA/Ethics/ucm079482.htm.

Describe the financial interest, indicate the type of investment, and if the interest was acquired as a form of compensation or other benefit derived from prior or current employment with a significantly regulated organization, check the employee benefit (EB) column. Check the column that indicates the value, and specify whether the financial interest is owned individually (I), by your spouse (S), or minor child(ren) (MC), or jointly (J). If held jointly with a spouse, minor child(ren), or others (O), indicate the co-owner(s), for example, J/S, J/MC, or J/O. Provide the name and relationship of any co-owners other than a spouse or minor child in the Comments section in Box 3 below. If you are a current employee, indicate in the Comments section, the date that you acquired the prohibited financial interest, for example, the date you were married, received a gift, or inherited an asset. If you acquired a prohibited financial interest inadvertently (e.g., a broker or financial advisor initiated the transaction) or under other circumstances, describe the situation in the Comments section in Box 3 below.

If you have already sold or divested the financial interest, describe in the Comments section in Box 3 below. If you are an employee who Is not required to file a public or confidential financial disclosure report, answer the questions in Box 2 below. Sign and date the certification. File this report with the FDA EIS within 30 days after your entry on duty. Current employees must file within 30 days after acquiring a prohibited financial interest.

Description	Type of Investment	EB	Value $15,000 or Less	Value Over $15,000	I/S/J MC/O
Example: Zyzex Pharmaceuticals	**Bonds**		√		**S**
Example: Medical Products Technology Co.	**Common stock in 401(k) pension from prior employment**	√		√	**I**
A.					
B.					
C.					
D.					
E.					
F.					
G.					
H.					
I.					
J.					

(continued on next page)

II. PROHIBITED FINANCIAL INTERESTS *(continued)*

2. QUESTIONS FOR NONFILERS

a. Does any equity interest in a significantly regulated organization listed above in item 1 on page 2 constitute 1% or more of the total outstanding equity of the organization?

☐ Yes *(If this box is checked, identify the financial interest and explain in the comments section in item 3 below.)*

☐ No

b. Does the actual value of holdings in the significantly regulated organizations listed in item 1 on page 2, when totaled, account for 50% or more of the total value of the combined investment portfolio of you, your spouse, and minor child(ren)?

☐ Yes

☐ No

3. COMMENTS *(If additional space is required, use the last page titled "Additional Space".)*

4. **CERTIFICATION**

I certify that the statements I have made on this form are true, complete, and correct to the best of my knowledge.

EMPLOYEE SIGNATURE	DATE

III. ETHICS AND INTEGRITY STAFF REVIEW

1. NAME OF REVIEWER	2. TITLE OF REVIEWER

3. CONTACT INFORMATION

TELEPHONE	FAX
( )	( )
CELL	EMAIL
( )	

4. ORGANIZATION

5. DETERMINATION

After review of the information disclosed in Part II, I have determined, pursuant to 5 CFR 5501.104, that the identified employee, spouse, and/or minor children must sell or otherwise divest the reported financial interests as follows:

☐ All Financial Interests Reported in Part II

☐ Only those Financial Interests Reported in the following Letter Blocks in Part II:

☐ No Divestiture By Employee Required *(Explain reason(s) in item 7 the Comments section.)*

Reviewer Signature	DATE

6. DIVESTITURE DATE *(Divestiture must be completed on or before the following date.)*

7. COMMENTS

IV. CERTIFICATE OF DIVESTITURE

1. **Capital Gains Tax Deferral**

Section 1043 of the Internal Revenue Code (26 U.S.C. 1043) and the regulations issued by the Office of Government Ethics (OGE) may allow an eligible person (including an employee, or the employee's spouse or minor or dependent children) to defer paying capital gains tax on property sold to comply with conflict of interest requirements. To defer the gains, an eligible person must obtain a legal document called a Certificate of Divestiture from the OGE Director **before** selling the property, after which the eligible person is required to reinvest the proceeds of the sale in "permitted property," which is either an obligation of the United States, such as a Treasury security, or a diversified investment fund, such as a diversified mutual fund. More information about Certificates of Divestiture can be found at http://inside.fda.gov:9003/downloads/EmployeeResources/Ethics/FDAEthicsProgram/UCM008857.doc .

Note that assets held in certain investment vehicles, such as an Individual Retirement Account (IRA) or 401(k), or other tax deferred assets not subject to the capital gains tax are ineligible for a Certificate of Divestiture.

2. **CD Election**

If you do not wish to pursue a Certificate of Divestiture, check this block ☐ **No CD**

You must sell or otherwise divest those financial interests identified by the Ethics and Integrity Staff (EIS) in Part II as prohibited and complete the necessary transaction(s) on or before the date specified by the Ethics and Integrity Staff in Part III, item 6. Complete Part V when you have fully divested all prohibited holdings, and then resubmit this form promptly to your EIS to document compliance.

If you are interested in requesting a Certificate of Divestiture because you anticipate realizing a capital gain on the sale of the prohibited holdings identified by the EIS in Part III, and you are prepared to abide by the limitations on reinvestments into permitted property, submit your request separately on the form prescribed for this purpose. Complete Part V of this form when you have fully divested all prohibited holdings, and then resubmit this form promptly to your EIS to document compliance.

V. COMPLIANCE

1. **Divestiture**

Date Divestiture Completed:

Describe the steps that you have taken to fulfill your divestiture obligation and indicate the date by which you completed all required transactions.

2. **CERTIFICATION**

I certify that I have sold or otherwise divested the prohibited financial interests identified by the EIS in Part III and that the statements I have made on this form are true, complete, and correct to the best of my knowledge.

EMPLOYEE SIGNATURE

DATE

PRIVACY ACT STATEMENT

The Ethics In Government Act, 5 U.S.C. App. § 101, *et seq.* , Executive Order 12674, as amended by Executive Order 12731, Sections 301 and 7301 of Title 5 of the U.S. Code, and Sections 2634.103, 5501.104, and 5502.106 of Title 5 of the Code of Federal Regulations authorize the collection of this information. Disclosure of this information is mandatory for those new entrant employees, except Special Government Employees, of the Food and Drug Administration (FDA) who are not subject to the public or confidential financial disclosure reporting requirements under 5 C.F.R. part 2634. Providing this information is also required for employees reassigned to the FDA and for those FDA employees who acquire a prohibited financial interest as defined at 5 C.F.R. § 5502.106(b)(2). Falsification of information or failure to file or report information required to be reported may subject the employee to disciplinary action. Knowing and willful falsification of information required to be reported may subject the employee to criminal prosecution. The primary use of this information Is to assist FDA supervisors, other management officials, and agency ethics officials in ensuring compliance with the prohibited holdings provisions of the HHS Supplemental Ethics Regulation applicable to FDA employees. The information may also be used to counsel employees concerning their ethics responsibilities and to prevent violations of the statutes, regulations, and executive orders governing employee conduct. The information is also requested, pursuant to 5 C.F.R. §§ 2638.203(b)(9),(10), and (11), for the purpose of evaluating ethics program administration, as well as the Department's supplemental ethics regulations, to determine their continued adequacy and effectiveness in relation to current agency responsibilities and to ensure that prompt and effective action Is taken to remedy violations or potential violations, or appearances thereof, of conflict of interest and related ethics provisions. Additionally, this information may be disclosed to: (1) the Office of Personnel Management, Office of Government Ethics, Merit Systems Protection Board, Office of the Special Counsel, Equal Employment Opportunity Commission, Federal Labor Relations Authority, Federal Service Impasses Panel, Federal Mediation and Conciliation Service, and an arbitrator, in carrying out their functions; (2) a Federal, State, or local agency charged with investigating or prosecuting violations of, or implementing, the law, in the event there is an indication of a violation or potential violation of civil, criminal or regulatory law; (3) a Federal, State, or local agency maintaining enforcement records or other pertinent records, such as current licenses, if necessary to obtain a record relevant to an agency decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant or other benefit; (4) the National Archives and Records Administration or the General Services Administration in records management inspections; (5) the Office of Management and Budget during legislative coordination on privacy relief legislation; (6) Federal agencies with power to subpoena other Federal agencies' records; (7) a court or party in court or Federal administrative proceeding if the Government is a party or in order to comply with a judge-issued subpoena; (8) private firms with which the Department may contract for the purpose of collating, analyzing, aggregating or otherwise refining records; (9) a Member of Congress or a Congressional office, pursuant to an inquiry made at the request of the individual who Is a subject of the record; (10) the Department of Justice in defense of litigation; and (11) contractors and other non-Government employees working for the Federal Government to accomplish a function related to an Office of Government Ethics Government-wide system of records. This confidential report will not be disclosed to any requesting person unless authorized by law. See the OGE/GOVT-2 Government-wide executive branch system of records.

ADDITIONAL SPACE

Identify the part and item number to which the additional information refers.

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Department of Health and Human Services
Office of the Secretary
Office of the General Counsel
Ethics Division
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