DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Collection Form

Report of Financial Interests and Other Relationships for Non-Employee Scientists at FDA

New Entrant ☐ Renewal ☐	Start Date:	Date Report Filed:
NON- EMPLOYEE SCIENTIST INFORMATION		
1. NAME (Last, First, MI)		
2. Center:	3. Office:	4. Division:
5. Non- Employee Program: ORISE ☐ Guest Scientist ☐ Traineeship ☐ Other ☐ (provide program name) _____		
6. Office Address		
7. City	8. State	9. Zip Code
10. Office Telephone	11. FAX	12. Cell
13. Email		
14. Name of Mentor/Sponsor (Last, First, MI):		
15. Title of Mentor/Sponsor:		
16. Mentor's/Sponsor's Telephone	17. Mentor's/Sponsor's FAX	18. Mentor's/Sponsor's Cell
19. Mentor's/Sponsor's email:		

II. FINANCIAL INTERESTS AND OTHER RELATIONSHIPS

As a condition of starting at FDA, you are required to submit the following information, to the best of your knowledge, and provide follow-up information to your Center and/or FDA, as necessary. You will be required to complete this form as part of your onboarding orientation at FDA with annual follow-up during your time at the agency.

For you, your spouse and your minor children, report all financial interests, such as stocks, bonds, stock options and other investments or ownership interests, in significantly regulated organizations (SROs) that you held as of the date that you entered with or were assigned to FDA. The term "significantly regulated organization (SRO)," (https://www.fda.gov/AboutFDA/WorkingatFDA/Ethics/ucm079482.htm) 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.

In addition, for you, your spouse and your minor children, report all interests in investments funds that have a stated a policy or practice of investing in companies that are SROs. The most common examples of such funds are mutual funds or ETFs that invest in a range of sectors (https://www.fda.gov/AboutFDA/WorkingatFDA/Ethics/ucm527948.htm).

Consult your Mentor/Sponsor 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 SROs can be found at: https://www.fda.gov/about-fda/ethics/prohibited-financial-interests-fda-employees

Describe the financial interest and indicate the type of investment. If the interest was acquired as a form of compensation or other benefit derived from prior or current employment with an SRO, 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 (0), indicate the co-owner(s), for example, J/S, J/MC, or J/O.

Note: If you acquire an interest in an SRO, a prohibited mutual fund, a privately held SRO or a mutual fund consisting of privately held SROs, after you have started at FDA, but before your annual review of the issues addressed in this form, you are required to report this information using this form to your Mentor/Sponsor within 30 days of acquiring the interest.

If none, check this box. ☐

Description	Type of Investment	EB	Value $15,000 or less	Value Over $15,000	I/S./J/MC/O
Example: Zyzex Pharmaceuticals	Bonds		X		S
Example: Medical Products Technology Co	Common Stock in 401(k) pension from prior employment	X		X	I

Description	Type of Investment	EB	Value $15,000 or less	Value Over $15,000	H/S/J/M/C/O
Example: Zyzex Pharmaceuticals	Bonds		X		S
Example: Medical Products Technology Co	Common Stock in 401(k) pension from prior employment	X		X	I

III. OTHER RELATIONSHIPS AND INTERESTS

Please indicate and report the following for yourself, your spouse, and/or your minor child(ren):

- An employment relationship with an SRO, including business ownership, employment, service as officer, director, trustee; and/or,
- service as consultant to an SRO; and/or,
- proprietary interest(s) in one or more product(s) regulated by FDA, including patent, trademark, copyright, or licensing agreement and/or,
- Other interest (please describe).

If none, check this box. ☐

Note: If you begin an employment relationship with and/or service as a consultant to an SRO or acquire proprietary interest(s) in one or more products regulated by FDA, including patent, trademark, copyright or licensing agreement and/or other interest, after you have started at FDA, but before your annual review of the issues addressed in this form you are required to report this information using this form to your Mentor/Sponsor within 30 days of beginning the relationship or acquiring the interest.

	Name of Organization	**Description of Interest or Relationship**	**Owner of Interest (Indicate I/S/J/MC/O)**	**Date Interest Acquired or Relationship Started**	**Date Interest Acquired or Relationship Terminated**
A.					
B.					
C.					
D.					
E.					
F.					
G.					
H.					

Signature	Date	Printed Name

Annual Review

If there are no changes, then certify below. If there are changes, then complete a new form.

Signature	Date	Printed Name
Signature	Date	Printed Name
Signature	Date	Printed Name
Signature	Date	Printed Name
Signature	Date	Printed Name
Signature	Date	Printed Name

PRIVACY ACT STATEMENT
Authority: The information collected in this form is provided to comply with the Privacy Act of 1974 (P.L. 93-579) for individuals seeking non-employee student, post-graduate or senior scientist training opportunities from the Food and Drug Administration.
Purpose and Uses: All information collected in this form is required to determine if there is potential conflict of interest with FDA assignments. Completed forms are used by the FDA Mentor and Ethics Staff to determine if there is conflict of interest. Information is also shared with the FDA personnel authorized to administer the program.
Effects of nondisclosure: Disclosure of the information is voluntary; however, collection of this information is necessary to continue with the FDA

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW. ***

The burden time for this collection of information is estimated to average 60 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services Food and Drug Administration Office of Operations Paperwork Reduction Act (PRA) Staff, PRAStaff@fda.hhs.gov.

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

LEGAL AND ETHICS REQUIREMENTS

The information collected in this form is in compliance with section 746(b) of the Food, Drug and Cosmetic Act.