

All FDA Employees:

Recently, the FDA Ethics and Integrity Staff have encountered issues dealing with family farm ownership. The FDA Conflict of Interest Review Board (COIRB), a Board delegated authority by the Commissioner to address matters of financial interest and outside activities, met to discuss the issues and has developed both an interim outcome and longer term strategy concerning the issue of family farm ownership by FDA employees and FDA's regulation of food.

As you know, Federal employees are governed by various conflict of interest statutes and standards of ethical conduct regulations. Employees in the Department of Health and Human Services are subject to additional regulations including the Supplemental Standards of Ethical Conduct for Employees of DHHS (5 CFR Part 5501). Section 5501.104(a) is specific to employees in the Food and Drug Administration and states that no employee or spouse or minor child of an employee shall have a financial interest in a "significantly regulated organization." This provision applies to employees who are required to complete and file a public or confidential financial disclosure report. Such employees are referred to as "filers" and comprise the majority of FDA employees. There are some exceptions for employees who are "non-filers."

A significantly regulated organization (SRO) is any entity that sells products that are regulated by the FDA and the sale of the products constitute ten percent of or more of the organization's gross annual sales. Under this definition, farms that sell agricultural products (crops and livestock), where the sale of these products account for ten percent or more of annual gross sales are significantly regulated organizations due to the sale of food items. The term "food," as defined in the Federal Food Drug and Cosmetic Act, Section 210(f), means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article. This definition also includes food animals. This same prohibited holding regulation applies equally to employees with financial interests in other FDA-regulated industries, including pharmaceuticals, medical devices, processed food, and certain tobacco products.

Because farms, due to the sale of food, are significantly regulated organizations, FDA filers may not have a financial interest in a farming operation. Even though these regulations have been in place for many years, there have been evolving legal interpretations on what constitutes an "FDA-regulated product" as applied to farm crops and food animals. Due to the current legal interpretations, employees who have an ownership interest in a farming operation are required to take steps to be in full compliance

with the above-described Federal regulation on prohibited financial interests. Options available to employees generally include: 1) Removing themselves, not including their spouse, as an owner in the farming operations; 2) changing the business operation of the farm to the renting of the land to another person; or , 3) requesting an exception from the Conflict of Interest Review Board (COIRB) that would allow the employee to retain an ownership interest in a farm.

Even though these are the options currently available, FDA is doing everything possible to minimize the impact of the prohibited holding regulation on employees including pursuing an amendment to the HHS Supplemental Regulations that would allow greater ownership of family farms. This is a detailed process that will require approval of both the Secretary of HHS and the Director of the Office of Government Ethics.

Accordingly, at a recent meeting of the COIRB, in recognition of the potential impact of the prohibited financial interest regulation on FDA employees, it was decided as an interim measure, that all current as well as future issues involving financial interests by employees in family farms will be held in abeyance pending the Supplemental amendment. Even though it is not clear at this time what the final amendment will include, employees with current interests in family farms will not be required to divest or otherwise alter their family farm operations during this abeyance period. However, as with all financial interests, employees are required to disqualify themselves from taking official actions that will directly affect their farming operation.

Once a final decision is made on the Supplemental amendment, cases involving interests in family farms will be addressed. Employees should continue to report their financial interests, including their interests in family farms, on their OGE 450, SF 278, or HHS 717-2 form as always. Once reported, the Ethics and integrity Staff will notify the employee of the COIRB ruling. If there are additional questions on this matter, please contact your designated Ethics Representative listed below:

OC, CBER Erika Jordan

[Erika.Jordan@FDA.HHS.GOV](mailto:Erika.Jordan@FDA.HHS.GOV) <mailto:[Erika.Jordan@FDA.HHS.GOV](mailto:Erika.Jordan@FDA.HHS.GOV)>

CDER, NCTR Erika Campbell

[Erika.Campbell@FDA.HHS.GOV](mailto:Erika.Campbell@FDA.HHS.GOV) <mailto:[Erika.Campbell@FDA.HHS.GOV](mailto:Erika.Campbell@FDA.HHS.GOV)>

CDER, CTP George Dapolito

[George.Dapolito@FDA.HHS.GOV](mailto:George.Dapolito@FDA.HHS.GOV) <mailto:[George.Dapolito@FDA.HHS.GOV](mailto:George.Dapolito@FDA.HHS.GOV)>

CDRH, CFSAN Jackie Walder

[Jaqueline.Walder@FDA.HHS.GOV](mailto:Jaqueline.Walder@FDA.HHS.GOV) <mailto:[Jaqueline.Walder@FDA.HHS.GOV](mailto:Jaqueline.Walder@FDA.HHS.GOV)>

CVM, ORA John Gomez

[John.Gomez@FDA.HHS.GOV](mailto:John.Gomez@FDA.HHS.GOV) <mailto:[John.Gomez@FDA.HHS.GOV](mailto:John.Gomez@FDA.HHS.GOV)>

Kimberly A. Holden

Assistant Commissioner for Management and Deputy Ethics Counselor