

Preventing Conflicts of Interest in the Executive Branch

# Exercise Booklet 207(a)(2)

**August 2020** 

#### **POST-EMPLOYMENT CHECKLIST**

#### **1. Name:** Ken Dickens

2. Date you anticipate leaving agency: My last day of service will be 10/01/XX

3. Most recent position title and pay grade/rate: Supervisory Counsel / GS-15

#### 4. Briefly Describe Your Duties:

I supervised staff in drafting regulations regarding drug marketing and advertising. My staff also provided legal support to Consumer Safety Officers and the Compliance Division in interpreting and implementing regulations in the course of their monitoring, auditing and investigative activities.

#### 5. Prospective employer (full name):

Wellness Pharmaceutical

#### 6. Describe Anticipated Position/Duties with Prospective Employer:

Legal Counsel—coordinate company's regulatory program, including reviewing and approving documentation to be submitted to governmental regulators. Point person for all communications regarding compliance with regulatory requirements in the areas of marketing, advertising and communications.

(*Note whether you are referring to your involvement or a subordinate's)	YES	NO
1. Have you or has anyone you supervise been involved in reviewing Investigational New Drug or New Drug applications?		x
2. Have you or has anyone you supervise been involved in reviewing or approving grant applications, or administering existing grants?		Х
3. Have you or has anyone you supervise been involved with monitoring or directing work under an existing grant or agreement between FDA and this company?		x
<ul> <li>4. Have you or has anyone you supervise participated in compliance monitoring involving this company? If so, please explain.</li> <li>Wellness was cited for marketing and advertising its drug Wellarest for additional uses beyond those for which it received FDA approval.</li> <li>My staff provided legal review support to the investigative team.</li> </ul>	*Х	
5. Have you or your subordinates had any other involvement with this company not referred to otherwise on this checklist? If so, please explain.		x

#### 207(a)(2)--Questions Relating to Ken Dickens' Post Employment

## Specific Party Matters Pending Under Official Responsibility/ Personal and Substantial Participation

What additional information do we need regarding the Wellness investigation to determine if any 207 restrictions apply?

What about the regulatory matters that Ken and his staff worked on?

#### Communications, Appearances & Behind-the-Scenes Assistance

May Ken communicate with FDA/HHS about the regulations he and his staff worked on?

May Ken submit comments on behalf of Wellness on new regulations HHS issues?

May Ken communicate with Government auditors and investigators about the Wellness compliance program?

#### Intent to Influence

What types of communications would be permitted/prohibited with respect to the compliance investigation?

What if Ken attends a meeting but does not speak?

#### **On Behalf of Any Other Person**

When, if ever, might Ken be deemed to be representing himself?

#### To or Before an Employee of the US

Are Ken's communications restricted only as to FDA?

#### Same Particular Matter in a Different Form

Might Ken have any restrictions with respect to any administrative or judicial proceeding against Wellness based upon the investigation?



### 18 U.S.C. 207 Post Employment Analysis Worksheet

#### Employee Name:

Yes	No No restrictions apply	
Personal and substantial participation (a)(1)	Pending under official responsibility (during last year) (a)(2)	
Communication Appearance with Intent to Influence	To or Before U.S.	On Behalf of 3 <sup>rd</sup> Party
5 CFR 2641.301		
	Personal and substantial participation (a)(1) Communication Appearance with Intent to Influence	No restriction         substantial         participation         (a)(1)         (a)(2)         Communication         Appearance with         Intent to Influence         U.S.