

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE



OFFICIAL WARNING  
VIOLATION OF FEDERAL REGULATIONS

CASE NUMBER:  
NJ170032

VIOLATOR:  
Ortho Clinical Diagnostics Inc.  
Customer# 182  
Registrant# 22-R-0064

ADDRESS (Street, City, State, ZIP Code):  
Manufacturing 1001 US Highway 202  
Raritan, NJ 18869

The U.S. Department of Agriculture has evidence that on or about the date(s) listed below, you or your organization committed violations of the following sections of the Code of Federal Regulations, Title 9:

**Date(s): December 1, 2016**

**§ 2.36 (a) Annual report.**

The reporting facility shall be that segment of the research facility, or that department, agency, or instrumentality the United States, that uses or intends to use live animals in research, tests, experiments, or for teaching. Each reporting facility shall submit an annual report to the AC Regional Director for the State where the facility is located on or before December 1 of each calendar year. The report shall be signed.

*The above is not intended to be an all-inclusive list. Please know that you are responsible for ensuring that your facility, animals, and property are in compliance with the Animal Welfare regulations.*

The Animal and Plant Health Inspection Service (APHIS) created federal regulations to ensure the welfare of animals and help prevent the spread of animal and plant pests and diseases. Since violations of the regulations can have serious and costly impacts that are detrimental to the public interest, APHIS is providing you with an Official Warning for the violation(s) described above. Any further violation of these federal regulations may result in the assessment of a civil penalty, criminal prosecution, or other sanctions. If you have any questions concerning this Official Warning or violation(s), please contact the APHIS official listed in this notice.

APHIS OFFICIAL (Name):  
Gerald Rushin

OFFICE ADDRESS:  
4700 River Road  
Riverdale, MD 30737

APHIS OFFICIAL (TITLE):  
Assistant Deputy Administrator  
Animal Care

DATE ISSUED: 14 March 2017  
TELEPHONE NO: (970) 494-7478

CERTIFIED MAIL RECEIPT NO:  
7013 2630 0002 2760 2119