



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
RESEARCH TRIANGLE PARK, NC 27711

SEP 28 2007

OFFICE OF  
AIR QUALITY PLANNING  
AND STANDARDS

Mr. Terrance Madden  
Grand Rapids District Office  
Michigan Department of Environmental Quality  
350 Ottawa Avenue NW  
Grand Rapids, MI 49503-2341

Dear Mr. Madden:

This is in response to your e-mail dated September 10, 2007, which requests the approval of an alternative test method for measuring hazardous air pollutant emissions (HAPs) at a Pharmacia-Upjohn pharmaceutical plant in Kalamazoo, MI. EPA Method 18 is required by 40 CFR Part 63, Subpart GGG, National Emission Standards for Pharmaceuticals Production, to demonstrate by definition (40 CFR 63.1251) that a vent is not a process vent because it is emitting less than 50 ppmv of HAPs. You are requesting that Pharmacia-Upjohn be allowed to use EPA Method 320 as an alternative to Method 18 for demonstrating that the HAP emissions from a vent are less than 50 ppmv.

Because Method 320 is capable of identifying and individually measuring HAPs just as Method 18 is, we believe that it is an appropriate alternative to Method 18. In addition, Method 320 has quality assurance procedures built into the method that make it self-validating, so there is no need for the source to demonstrate by Method 301 that it is a valid method for this kind of source. Therefore we are approving the use of Method 320 as an alternative to Method 18 for the purpose of demonstrating that a vent is not a process vent as defined in 40 CFR 63.1251. Because we believe that this alternative is acceptable for use at any pharmaceutical plant, this approval to use Method 320 as an alternative to Method 18 may be used by any company that owns a pharmaceutical plant if they choose to use it. We will announce on EPA's web site (at <http://www.epa.gov/ttn/emc/tmethods.html#CatB>) that our approval of this alternative to Method 18 is broadly applicable to all pharmaceutical plants. If you need further assistance, please contact Gary McAlister at (919) 541-1062.

Sincerely,

A handwritten signature in black ink that reads "Conniesue B. Oldham".

Conniesue B. Oldham, Ph.D., Group Leader  
Measurement Technology Group