Drug Status Report

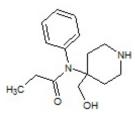
Drug: O-Demethylnoralfentanil

Drug Name Status: O-Demethylnoralfentanil is the common name

Other Names: O-Desmethylnoralfentanil

Chemical Name: N-[4-(hydroxymethyl)piperidin-4-yl]-N-phenylpropanamide

Chemical structure:



Molecular Formula: C₁₅H₂₂N₂O₂

Pharmacological class / Application: fentanyl related substance

International status:

US: The substance is not currently listed explicitly on the schedules to the US Controlled Substances Act and is not mentioned on the DEA website.

United Nations: The substance is not listed on the Yellow List - List of Narcotic Drugs under International Control nor the Green List - List of Psychotropic Substances under International Control.

Canadian Status: It has been claimed¹ that O-demethylnoralfentanil is a metabolite of alfentanil although others² have not mentioned it. However, its status as a metabolite is irrelevant to its status as a member of the fentanyl family as item 16 of Schedule I is "Fentanyls, their salts, derivatives and analogues and salts of derivatives and analogues." O-Demethylnoralfentanil is structurally related to the fentanyls and therefore might be considered an analogue of alfentanil.

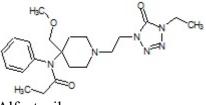
The structures of fentanyl and alfentanil are shown below. A review of the current family of fentanyls indicates that all members have one common root structure that is shown below. In

¹ <u>http://www.ndaa.org/pdf/ntlc_opioids.pdf</u>

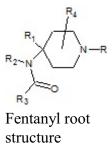
² Klees TM, Sheffels P, Thummel KE, Kharasch ED, Anesthesiology. 2005 Mar;102(3):550-6.

order to consider a substance a member of the fentanyl family of drugs and hence included in this item of Schedule I its structure must contain the elements of this root structure.





Alfentanil



where

R= ethyl group substituted variously at the 1 and 2 position

R₁= hydrogen, methoxymethyl or carboxylate alkyl ester

 R_2 = phenyl or substituted phenyl

 $R_3 = alkyl$

R₄= hydrogen or alkyl

The structure of O-demethylnoral fentanil does not comply with the requirements for R or R₁.

Recommendation: O-Demethylnoralfentanil is not included in Item 16 of Schedule I and is not a controlled substance.

August 21, 2008 (Revised September 8, 2008)