

Justification for emergency action for DEA Form 224c  
Revision of DEA Information Collection 1117-0014

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Pub. L. 110-425) was enacted on October 15, 2008. The Ryan Haight Act amended the Controlled Substances Act by adding various provisions to prevent the illegal distribution and dispensing of controlled substances by means of the Internet. The law becomes effective April 13, 2009.

The Ryan Haight Act requires DEA-registered pharmacies that fall within the definition of an online pharmacy (21 U.S.C. 802(52), 21 CFR 1300.04(h)) to apply for a modified registration authorizing the pharmacy to dispense controlled substances by means of the Internet (21 U.S.C. 823(f), 21 CFR 1301.11(b)). The Application for Modification of Registration for Online Pharmacies (DEA-224c) will allow pharmacies to apply for a modified registration via an online process.

If the anticipated activities of a pharmacy will render it an online pharmacy within the meaning of the Act, that pharmacy must submit to DEA an application for a modified registration as early as possible, since it will not be permitted to engage in the activities of an online pharmacy until DEA has approved such application. To expedite this process, DEA has established an online application process for registrants to apply for such modification of registration.

The application for a modified registration must be approved and a Certificate of Registration indicating the modification must be issued before the online pharmacy may engage in any activity of an online pharmacy. Thus, it is critical that this collection be approved as expeditiously as possible so that the online application function will be in place to allow time for online pharmacies to apply for the modification and for DEA to review the applications.

The requirement for online pharmacies to obtain a modified registration is a key aspect of the Ryan Haight Act and the rule promulgating the implementing regulations. Congress contemplated it would be necessary for DEA to issue regulations on an interim basis to implement the Act given the 180 days between enactment of the Act and its effective date. Congress recognized it would be contrary to the public interest to delay the promulgation of regulations in a manner that would prevent implementation of the Act upon its effective date.

As of April 13, 2009, it will be illegal under federal law to deliver, distribute, or dispense a controlled substance by means of the Internet, unless an online pharmacy holds a modified registration. It is essential that the online application (DEA-224c) capability be fully operational as soon as possible to allow DEA to carry out its functions as a law enforcement agency, and to meet the statutory deadline of the Ryan Haight Act. Consequently, DEA is requesting this information collection be considered on an emergency basis. A delay in the revision of this information collection will prevent the Application for Modification of Registration for Online Pharmacies (DEA-224c) from being operational prior to the April 13, 2009 effective date of the law. If DEA does not have DEA-224c in place prior to the statutory deadline, online pharmacies will not be able to apply for the modified registration allowing them to conduct business as an online pharmacy and DEA will be in violation of the statute.