

PART 1301 — REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

REGISTRATION

§1301.11 Persons required to register; requirement of modification of registration authorizing activity as an online pharmacy.

(a) Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration unless exempted by law or pursuant to **§§1301.22 through 1301.26**. Except as provided in paragraph (b) of this section, only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration.)

(b) As provided in sections 303(f) and 401(h) of the Act (**21 U.S.C. 823(f)** and **841(h)**), it is unlawful for any person who falls within the definition of "online pharmacy" (as set forth in section 102(52) of the Act (21 U.S.C. 802(52)) and **§1300.04(h)** of this chapter) to deliver, distribute, or dispense a controlled substance by means of the Internet if such person is not validly registered with a modification of such registration authorizing such activity (unless such person is exempt from such modified registration requirement under the Act or this chapter). The Act further provides that the Administrator may only issue such modification of registration to a person who is registered as a pharmacy under section 303(f) of the Act (21 U.S.C. 823(f)). Accordingly, any pharmacy registered pursuant to **§1301.13** of this part that falls within the definition of an online pharmacy and proposes to dispense controlled substances by means of the Internet must obtain a modification of its registration authorizing such activity following the submission of an application in accordance with **§1301.19** of this part. This requirement does not apply to a registered pharmacy that does not fall within the definition of an online pharmacy set forth in **§1300.04(h)**. Under the Act, persons other than registered pharmacies are not eligible to obtain such a modification of registration but remain liable under section 401(h) of the Act (21 U.S.C. 841(h)) if they deliver, distribute, or dispense a controlled substance while acting as an online pharmacy without being validly registered with a modification authorizing such activity.

[74 FR 15621, Apr. 6, 2009]