Extracted by GlobalMSDS Ltd 9 January 2019

PART 1316 — ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES

Subpart A — Administrative Inspections

§1316.03 Authority to make inspections.

In carrying out his functions under the Act, the Administrator, through his inspectors, is authorized in accordance with sections 510 and 1015 of the Act **(21 U.S.C. 880** and **965)** to enter controlled premises and conduct administrative inspections thereof, for the purpose of:

(a) Inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept or made under the Act and regulations promulgated under the Act, including, but not limited to, inventory and other records required to be kept pursuant to **part 1304** of this chapter, order form records required to be kept pursuant to **part 1306** of this chapter, prescription and distribution records required to be kept pursuant to **part 1306** of this chapter, records of listed chemicals, tableting machines, and encapsulating machines required to be kept pursuant to **part 1310** of this chapter, import/export records of listed chemicals required to be kept nursuant to **part 1310** of this chapter, shipping records identifying the name of each carrier used and the date and quantity of each shipment, and storage records identifying the name of each warehouse used and the date and quantity of each storage.

(b) Inspecting within reasonable limits and to a reasonable manner all pertinent equipment, finished and unfinished controlled substances, listed chemicals, and other substances or materials, containers, and labeling found at the controlled premises relating to this Act;

(c) Making a physical inventory of all controlled substances and listed chemicals on-hand at the premises;

(d) Collecting samples of controlled substances or listed chemicals (in the event any samples are collected during an inspection, the inspector shall issue a receipt for such samples on DEA Form 400 to the owner, operator, or agent in charge of the premises);

(e) Checking of records and information on distribution of controlled substances or listed chemicals by the registrant or regulated person (i.e., has the distribution of controlled substances or listed chemicals increased markedly within the past year, and if so why);

(f) Except as provided in **§1316.04**, all other things therein (including records, files, papers, processes, controls and facilities) appropriate for verification of the records, reports, documents referred to above or otherwise bearing on the provisions of the Act and the regulations thereunder.

[36 FR 7820, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 51 FR 5319, Feb. 13, 1986; 55 FR 50827, Dec. 11, 1990; 60 FR 32465, June 22, 1995; 77 FR 4238, Jan. 27, 2012]