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THE INFLUENCE AND IMPACT OF 21 CFR (US FDA) IN PHARMACEUTICAL INDUSTRY

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ABSTRACT

The influence of 21 CFR in pharmaceutical industry clarifies the pharmaceutical regulations which had been built from years of experience with FDA and other global regulatory authorities, and knowledge of what regulators expect from pharma companies. In order to ensure quality and safety are maintained, Matrices develops strategies that pinpoint where compliance improvements are needed and how to best take action. Rather than focusing on individual symptoms, a broader approach to locating and remediating systemic quality, regulatory, and compliance issues which gives perfect output**.** Title 21 is the portion of the CFR that governs food and drugs within the United States for the Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), and the Office of National Drug Control Policy (ONDCP). This retrospective review works reveals about electronic records, Clinical trials, GLP, drug advertising, marketing, specific requirements of new drugs, OTC, controlled substances, various schedule of drugs from I to V and government wide requirements for drug free work places. This review article highly focuses on drug regulations as per USFDA norms.

KEYWORD: USFDA - United States for the Food and Drug Administration; GLP – Good Laboratory Practice, OTC – Over the counter.

INTRODUCTION

The Code of Federal Regulations is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. The Code is divided into 50 titles which represent broad areas subject to Federal regulation. Each title is divided into chapters which usually bear the name of the issuing agency. Each chapter is further subdivided into parts covering specific regulatory areas.

The Code of Federal Regulations is kept up to date by the individual issues of the Federal Register. These two publications must be used together to determine the latest version of any given rule. To determine whether a Code volume has been amended since its revision date (in this case, April 1, 2012), consult the ‘‘List of CFR Sections Affected (LSA),’’ which is issued monthly, and the ‘‘Cumulative List of Parts Affected,’’ which appears in the Reader Aids section of the daily Federal Register. These two lists will identify the Federal Register page number of the latest amendment of any given rule.

21 CFR is divided into three different chapters as mentioned below

- **Chapter I**-Food and Drug Administration
- **Chapter II**-Drug Enforcement Administration
- **Chapter III**-Office of National Drug Control Policy.

1. Chapter I-Food and Drug Administration.

Table. 1: Food and Drug Administration.

Sl. No	Chapter's	Concepts
1.	Subchapter A	General (parts 1 - 99)
2.	Subchapter B	Food for Human Consumption (parts 100 - 191-199)
3.	Subchapter C	Drugs: General (parts 200 - 299)
4.	Subchapter D	Drugs for Human use (parts 300 - 370-499)
5.	Subchapter E	Animal drugs, feeds, and related products (parts 500 - 590-599)
6.	Subchapter F	Biologics (parts 600 - 680)
7.	Subchapter G	Cosmetics (parts 700 - 741-799)
8.	Subchapter H	Medical Devices (parts 800 - 898)
9.	Subchapter I	Mammography quality standards act (part 900)
10.	Subchapter J	Radiological health (parts 1000 - 1050)
11.	Subchapter K	Tobacco products (parts 1100 - 1150)
12.	Subchapter L	Regulations under certain other acts administered by the food and drug administration (parts 1210 - 1272-1299)

2. Chapter II — Drug Enforcement Administration

Table. 2: Drug Enforcement Administrations.

Sl. No	Chapter's	Concepts
1.	Part 1300	Definitions
2.	Part 1301	Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances (§§ 1301.01 - 1301.93)
3.	Part 1302	Labelling and packaging requirements for controlled substances (§§ 1302.01 - 1302.07)
4.	Part 1303	Quotas (§§ 1303.01 - 1303.37)
5.	Part 1304	Records and reports of Registrants (§§ 1304.01 - 1304.55)
6.	Part 1305	Orders for schedule I and II controlled substances (§§ 1305.01 - 1305.29)
7.	Part 1306	Prescriptions (§§ 1306.01 - 1306.27)
8.	Part 1307	Miscellaneous (§§ 1307.01 - 1307.31)
9.	Part 1308	Schedules of controlled substances (§§ 1308.01 - 1308.49)
10.	Part 1309	Registration of manufacturers, distributors, importers and exporters of list chemicals (§§ 1309.01 - 1309.73)
11.	Part 1310	Records and Reports of listed chemicals and certain machines; importation and exportation of certain machines (§§ 1310.01 - 1310.21)
12.	Part 1311	Requirements for electronic orders and prescriptions (§§ 1311.01 - 1311.305)
13.	1312	Importation and Exportation of controlled substances (§§ 1312.01 - 1312.47)
14.	1313	Importation and Exportation of list i and list ii chemicals (§§ 1313.01 - 1313.57)
15.	1314	Retail sale of Scheduled listed chemical products (§§ 1314.01 - 1314.155)
16.	1315	Importation and Production quotas for ephedrine, pseudoephedrine, and phenylpropanolamine (§§ 1315.01 - 1315.62)
17.	1316	Administrative Functions, Practices, and Procedures (§§ 1316.01 - 1316.68)
18.	1317	Disposal (§§ 1317.01 - 1317.95)
19.	1321	Dea mailing addresses (§ 1321.01)
20.	1322-99	[reserved]

3. Chapter III — Office of National Drug Control Policy

Table. 3: Office of National Drug Control Policy.

Sl. No	Chapter's	Concepts
1.	Part 1400	[Reserved]
2.	Part 1401	Public availability of information (§§ 1401.1 - 1401.13)
3.	Part 1402	Mandatory declassification review (§§ 1402.1 - 1402.7)
4.	Part 1403	[Reserved]

4. Chapter I

4.1 Food and Drug Administration

Table 4: Food and Drug Administration.

Sl. No	Sections.	Title
1.	**Section 11**	electronic records and electronic signature related
2.	**Section 50**	Protection of human subjects in clinical trials
3.	**Section 54**	Financial Disclosure by Clinical Investigators
4.	**Section 56**	Institutional Review Boards that oversee clinical trials
5.	**Section 58**	Good Laboratory Practices (GLP) for nonclinical studies

4.2 The 200 and 300 series are regulations pertaining to pharmaceuticals

Table 5: The 200 and 300 series are regulations pertaining to pharmaceuticals.

Sl. No	Sections.	Title
1.	Section 202-203	Drug advertising and marketing.
2.	Section 210 et al.,	c GMPs for pharmaceuticals
3.	Section 310	Requirements for new drugs
4.	Section 328	Specific requirements for over-the-counter (OTC) drugs

4.3. Section 11

4.3.1 Guidance for Industry Part 11, Electronic Records; Electronic Signatures — Scope and Application: This guidance is intended to describe the Food and Drug Administration's (FDA's) current thinking regarding the scope and application of part 11 of Title 21 of the Code of Federal Regulations; Electronic Records; Electronic Signatures (21 CFR Part 11). This document provides guidance to persons who, in fulfilment of a requirement in a statute or another part of FDA's regulations to maintain records or submit information to FDA, have chosen to maintain the records or submit designated information electronically and, as a result, have become subject to part 11. Part 11 applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any records requirements set forth in Agency regulations.[1]

Part 11 applies to drug makers, medical device manufacturers, biotech companies, biologics developers, CROs, and other FDA-regulated industries, with some specific exceptions. It requires that they implement controls, including audits, system validations, audit trails, electronic signatures, and documentation for software and systems involved in processing the electronic data that FDA predicate rules require them to maintain. A predicate rule is any requirement set forth in the Federal Food, Drug and Cosmetic Act, the Public Health Service Act, or any FDA regulation other than Part 11.

4.3.2 Details of Approach – Scope of section 11

Under the narrow interpretation of the scope of part 11, with respect to records required to be maintained under predicate rules or submitted to FDA, when persons choose to use records in electronic format in place of paper format, part 11 would apply. On the other hand, when persons use computers to generate paper printouts of electronic records, and those paper records meet all the requirements of the applicable predicate rules and persons rely on the paper records to perform their regulated activities, FDA would generally not consider persons to be "using electronic records in lieu of paper records" under 11.2(a) and 11.2(b). In these instances, the use of computer systems in the generation of paper records would not trigger part 11.

4.3.3 Approach to Specific Part 11 Requirements

a). Validation: Validation of computer system, USFDA recommend that you base your approach on a justified and documented risk assessment and a determination of the potential of the system to affect product quality and safety, and record integrity. For instance, validation would not be important for a word processor used only to generate SOPs.

Further guidance on validation of computerized systems, see FDA's guidance for industry and FDA staff General Principles of Software Validation and also industry guidance such as the GAMP 4 Guide (See References).

b). Audit Trail

The Agency intends to exercise enforcement discretion regarding specific part 11 requirements related to computer-generated, time-stamped audit trails (§ 11.10 (e), (k) (2) and any corresponding requirement in §11.30). Persons must still comply with all applicable predicate rule requirements related to documentation of, for example, date (e.g., § 58.130(e)), time, or sequencing of events, as well as any requirements for ensuring that changes to records do not obscure previous entries.

c). Legacy Systems: This means that the Agency does not intend to take enforcement action to enforce compliance with any part 11 requirements if all the following criteria are met for a specific system.

- The system was operational before the effective date.
- The system met all applicable predicate rule requirements before the effective date.
- The system currently meets all applicable predicate rule requirements.

- You have documented evidence and justification that the system is fit for its intended use (including having an acceptable level of record security and integrity, if applicable).

d). Copies of Records

Supply copies of electronic records by
Producing copies of records held in common portable formats when records are maintained in these formats Using established automated conversion or export methods, where available, to make copies in a more common format (examples of such formats include, but are not limited to, PDF, XML, or SGML).

e). Record Retention

The agency suggest that your decision on how to maintain records be based on predicate rule requirements and that you base your decision on a justified and documented risk assessment and a determination of the value of the records over time.

4.3.4 21 CFR Part 211.[2]

- Subpart A - General Provisions (211.1 - 211.3)
- Subpart B - Organization and Personnel (211.22 - 211.34)
- Subpart C - Buildings and Facilities (211.42 - 211.58)
- Subpart D - Equipment (211.63 - 211.72)
- Subpart E - Control of Components and Drug Product Containers and Closures (211.80 - 211.94)
- Subpart F - Production and Process Controls (211.100 - 211.115)
- Subpart G - Packaging and Labelling Control (211.122 - 211.137)
- Subpart H - Holding and Distribution (211.142 - 211.150)
- Subpart I - Laboratory Controls (211.160 - 211.176)
- Subpart J - Records and Reports (211.180 - 211.198)
- Subpart K - Returned and Salvaged Drug Products (211.204 - 211.208)

The Food and Drug Administration (FDA) rule for electronic records and signatures became effective and enforceable on August 20, 1997. The rule has two main areas of enforcement: electronic records and electronic signatures.

The rule applies to all areas of Title 21 of the Code of Federal Regulation (CFR) for all manufactured drugs and medical products distributed in the United States of America. Detailed procedural and technical requirements are given for both electronic signatures and electronic records. Some of these include
– Ability to discern invalid records
– Ability to generate electronic copies of records
– Automatic generation of audit trail
– Access controls
– Secure link of signatures to records
– Use of unique secure signatures.[3]

4.4 Section 50

4.4.1 CFR - Code of Federal Regulations Title 21

a). Purpose

This part applies to all clinical investigations regulated by the Food and Drug Administration under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Additional specific obligations and commitments of, and standards of conduct for, persons who sponsor or monitor clinical investigations involving particular test articles may also be found in other parts (e.g., parts 312 and 812). Compliance with these parts is intended to protect the rights and safety of subjects involved in investigations filed with the Food and Drug Administration pursuant to sections 403, 406, 409, 412, 413, 502, 503, 505, 510, 513-516, 518-520, 721, and 801 of the Federal Food, Drug, and Cosmetic Act and sections 351 and 354-360F of the Public Health Service Act.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

4.5 Section 54 -- financial disclosure by clinical investigators

4.5.1 Purpose: The Food and Drug Administration (FDA) evaluates clinical studies submitted in marketing applications, required by law, for new human drugs and biological products and marketing applications and reclassification petitions for medical devices.

The agency reviews data generated in these clinical studies to determine whether the applications are approvable under the statutory requirements. FDA may consider clinical studies inadequate and the data inadequate if, among other things, appropriate steps have not been taken in the design, conduct, reporting, and analysis of the studies to minimize bias. One potential source of bias in clinical studies is a financial interest of the clinical investigator in the outcome of the study because of the way payment is arranged (e.g., a royalty) or because the investigator has a proprietary interest in the product (e.g., a patent) or because the investigator has an equity interest in the sponsor of the covered study. This section and conforming regulations require an applicant whose submission relies in part on clinical data to disclose certain financial arrangements between sponsor(s) of the covered studies and the clinical investigators and certain interests of the clinical investigators in the product under study or in the sponsor of the covered studies. FDA will use this information, in conjunction with information about the design and

purpose of the study, as well as information obtained through on-site inspections, in the agency's assessment of the reliability of the data.[4]

4.6 Section 56

4.6.1 Institutional Review Boards

a) This part contains the general standards for the composition, operation, and responsibility of an Institutional Review Board (IRB) that reviews clinical investigations regulated by the Food and Drug Administration under sections 505(i) and 520(g) of the act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and colour additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Compliance with this part is intended to protect the rights and welfare of human subjects involved in such investigations.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.[5]

4.7 Section 58

This part prescribes good laboratory practices for conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and colour additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products. Compliance with this part is intended to assure the quality and integrity of the safety data filed pursuant to sections 406, 408, 409, 502, 503, 505, 506, 510, 512-516, 518-520, 721, and 801 of the Federal Food, Drug, and Cosmetic Act and sections 351 and 354-360F of the Public Health Service Act.

(References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

4.8 Section 202-203

An alternative way for drug companies to provide risk information about a drug in a broadcast ad. Drug companies generally must include all of a drug's risk information in a product claim ad. In print ads, they usually do this in the "brief summary." This brief summary would take many minutes to read or scroll down a TV screen. The law allows broadcast ads to include only the most important risk information if the ads tell viewers or listeners how to get the full FDA-approved prescribing information, which has all the drug's risks. To meet the "adequate provision" requirement, the broadcast ad must provide ways to find the drug's FDA-approved prescribing information.

Broadcast ads can meet the "adequate provision" requirement by giving a number of sources for finding a drug's prescribing information. These include:

- A healthcare provider (for example, a doctor)
- A toll-free telephone number
- The current issue of a magazine that contains a print ad
- A Web site address.[6]

4.9 Section 210 c GMP for pharmaceuticals

This guidance is intended to help manufacturers implementing modern quality systems and risk management approaches to meet the requirements of the Agency's current good manufacturing practice (CGMP) regulations (2l CFR parts 210 and 211). The guidance describes a comprehensive quality systems (QS) model, highlighting the model's consistency with the CGMP regulatory requirements for manufacturing human and veterinary drugs, including biological drug products. The guidance also explains how manufacturers implementing such quality systems can be in full compliance with parts 210 and 211. This guidance is not intended to place new expectations on manufacturers, nor to replace the CGMP requirements. Readers are advised to always refer to parts 210 and 211 to ensure full compliance with the regulations.[7]

4.10 Six-system Inspection Model

The FDA's Drug Manufacturing Inspection Compliance Program, which contains instructions to FDA personnel for conducting inspections, is a systems-based approach to inspection and is very consistent with the robust quality system model presented in this guidance. The diagram below shows the relationship among the six systems: the quality system and the five manufacturing systems. The quality system provides the foundation for the manufacturing systems that are linked and function within it. The quality system model described in this guidance does not consider the five manufacturing systems as discrete entities, but instead integrates them into appropriate sections of the model. Those familiar with the six-system inspection approach will see organizational differences in this guidance; however, the inter-relationship should be readily apparent.

4.11 Section 310 new drugs.

A new drug may not be approved for marketing unless it has been shown to be safe and effective for its intended use(s). After approval, the applicant is required to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds under section 505(e) of the act for suspending or withdrawing approval of the application. Some drugs, because of the nature of the condition for which they are intended, must be used for long periods of time--even a lifetime. To acquire necessary data for determining the safety and effectiveness of long-term use of such drugs, extensive animal and clinical tests are required as a condition of

approval. Nonetheless, the therapeutic or prophylactic usefulness of such drugs may make it inadvisable in the public interest to delay the availability of the drugs for widespread clinical use pending completion of such long-term studies. In such cases, the Food and Drug Administration may approve the new drug application on condition that the necessary long-term studies will be conducted and the results recorded and reported in an organized fashion.

A proposal to require additional or continued studies with a drug for which a new drug application has been approved may be made by the Commissioner on his own initiative or on the petition of any interested person, pursuant to part 10 of this chapter. Prior to issuance of such a proposal, the applicant will be provided an opportunity for a conference with representatives of the Food and Drug Administration. When appropriate, investigators or other individuals may be invited to participate in the conference. All requirements for special studies, records, and reports will be published in 310.304.[8]

5. Chapter II – Drug Enforcement Administration

Table. 6: Drug Enforcement Administration.

Sl. No	Sections.	Title
1.	**Section - 1308**	Schedules of controlled substances
2.	**Section 1308.03(a)**	Administrative controlled Substances Code Number
3.	**Section 1308.11**	List of Schedule I drugs
4.	**Section 1308.12**	List of Schedule II drugs
5.	**Section 1308.13**	List of Schedule III drugs
6.	**Section 1308.14**	List of Schedule IV drugs
7.	**Section 1308.15**	List of Schedule V drugs

5. Section 1308 -- schedules of controlled substances

Schedules of controlled substances established by section 202 of the Act (21 U.S.C. 812) and nonnarcotic substances, chemical preparations, veterinary anabolic steroid implant products, prescription products, anabolic steroid products, and cannabis plant material and products made therefrom that contain tetrahydrocannabinols excluded pursuant to section 201 of the Act (21 U.S.C. 811), as they are changed, updated, and republished from time to time, are set forth in this part.[9]

5.1 Section 1308.03 -- schedules of controlled substances

Each controlled substance, or basic class thereof, has been assigned an "Administration Controlled Substances Code Number" for purposes of identification of the substances or class on certain Certificates of Registration issued by the Administration pursuant to 1301.35 of this chapter and on certain order forms issued by the Administration pursuant to 1305.05(d) of this chapter. Applicants for procurement and/or individual manufacturing quotas must include the appropriate code number on the application as required in 1303.12(b) and 1303.22(a) of this chapter. Applicants for import and export permits must include the appropriate code number on the application as required in 1312.12(a) and 1312.22(a) of this chapter. Authorized registrants who desire to import or export a controlled substance for which an import or export permit is not required must include the appropriate Administration Controlled Substances Code Number beneath or beside the name of each controlled substance listed on the DEA Form 236 (Controlled Substance Import/Export Declaration) which is executed for such importation or exportation as required in 1312.18(c) and 1312.27(b) of this chapter.[10]

5.2 Section 1308.11 - List of schedule I drugs

Schedule I drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse. Some examples of Schedule I drugs are: heroin, lysergic acid diethylamide (LSD), marijuana (cannabis),3,4methylenedioxymethamphetamine (ecstasy), methaqualone, and opeyote.[11]

a). Opiates. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical de signation.

b). Opium derivatives. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

c). Depressants. Unless specifically accepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

d). Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the

central nervous system, including its salts, isomers, and salts of isomers.

e). Cannabimimetic agents. Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, or which contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

5.3 Schedule 1308.12 - List of schedule II drugs

Schedule II drugs, substances, or chemicals are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous. Some examples of Schedule II drugs are: Combination products with less than 15 milligrams of hydrocodone per dosage unit (Vicodin), cocaine, methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (Oxy Contin), fentanyl, Dexedrine, Adderall, and Ritalin.

(a) Schedule II shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the Controlled Substances Code Number set forth opposite it.

(b) Substances, vegetable origin or chemical synthesis. Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis of Opium, Opiates, depressants, stimulant, cannabimimmetic.

5.4 Schedule 1308.13 List of schedule III drugs

Schedule III drugs, substances, or chemicals are defined as drugs with a moderate to low potential for physical and psychological dependence. Schedule III drugs abuse potential is less than Schedule I and Schedule II drugs but more than Schedule IV. Some examples of Schedule III drugs are: Products containing less than 90 milligrams of codeine per dosage unit (Tylenol with codeine), ketamine, anabolic steroids, testosterone.

(b) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, positional, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

(c) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system
(D) Nalorphine 9400.
(e) Narcotic Drugs. Unless specifically excepted
(f) Anabolic Steroids.
(g) Hallucinogenic substances.[12]

5.5 1308.14 List of schedule IV drugs

Schedule IV drugs, substances, or chemicals are defined as drugs with a low potential for abuse and low risk of dependence. Some examples of Schedule IV drugs are: Xanax, Soma, Darvon, Darvocet, Valium, Ativan, Talwin, Ambien, Tramadol.

(a) Schedule IV shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

(b) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below.
(c) Depressants.
(d) Fenfluramine.
(f) Stimulants.[13]

5.6 1308.15 – List of schedule V drugs: Schedule V drugs, substances, or chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes. Some examples of Schedule V drugs are cough preparations with less than 200 milligrams of codeine or per 100 milliliters (Robitussin AC), Lomotil, Motofen, Lyrica, Parepectolin.

6. Chapter III – Office of National Drug Control Policy: Schedule III shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it Schedule III shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

Table. 7.

Sl. No	Sections.	Title
1.	**Section - 1405**	Government wide requirements for drug-free workplaces.

CONCLUSION

The *Code of Federal Regulations* (*CFR*) is the codification of the general and permanent rules and regulations (sometimes called administrative law) published in the *Federal Register* by the executive departments and agencies of the federal government of the United States. The CFR is divided into 50 titles that represent broad areas subject to federal regulation. The CFR annual edition is the codification of the general and permanent rules published by the Office of the Federal Register (part of the National Archives and Records Administration) and the Government Publishing Office. In addition to this annual edition, the CFR is published in an unofficial format online on the Electronic CFR website, which is updated daily.

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