PROCEDURES

OFFICE OF THE CENTER DIRECTOR

FORECASTING SCHEDULE I AND II SUBSTANCE AND DRUG NEEDS

Table of Contents

PURPOSE

This MAPP establishes specific responsibilities in the Center for Drug Evaluation and Research (CDER) for offices reporting usage data applied in forecasting medical need for schedule I and schedule II substances, additional controlled drugs and list I chemicals to the Drug Enforcement Administration (DEA).

BACKGROUND

The Department of Health and Human Services (HHS) is responsible for providing the DEA with annual estimates of the amounts of specific schedule I and schedule II substances, additional controlled drugs[1], and list I chemicals that will be needed for medical and scientific use. The DEA relies on these estimates to establish annual manufacturing quotas for the substances and drugs [Controlled Substances Act (CSA) and the Public Health Services Act (PHSA)]. The Controlled Substance Staff (CSS) in CDER is responsible for ensuring that DEA's manufacturing quotas for schedule I and schedule II substances, additional controlled drugs, and list I chemicals are sufficient to meet medical and scientific needs. CSS gathers quantitative information from offices in CDER and from the Drug Shortage Staff for all schedule I and II substances, additional

[1] The DEA has certain reporting mandates under international treaties. In accordance with Article 19 of the Single Convention on Narcotic Drugs, 1961, and Article 16 of the Convention on Psychotropic Substances, 1971, the DEA must report the quantities of internationally controlled substances manufactured in the United States, the total quantities exported and imported, and the United States' assessment of the maximum quantity of controlled substances imported into the United States. Therefore, the DEA requests that HHS provide estimates of the quantities which will be required to meet the legitimate medical and scientific domestic needs for the substances termed “additional controlled drugs” in this MAPP. The specific “additional controlled drugs” are defined annually in the request letter from DEA to HHS.

controlled drugs, and list I chemicals INDs), supplemental NDAs (sNDAs), or that are discontinued or in short supply. CSS provides this information to the DEA. The specific schedule I and schedule II substances, additional controlled drugs and list I chemicals for which DEA requests usage data are hereafter referred to as "quota-relevant drug substances".

RESPONSIBILITIES

1. The Controlled Substances Staff (CSS) will:

- Send out consult requests to the appropriate CDER offices (e.g., Office of New Drugs Review Divisions, Office of Surveillance and Epidemiology, Office of Biostatistics Office of Generic Drugs, Drug Shortage Staff and other offices as needed), FDA's Center for Veterinary Medicine (CVM), and other government agencies, requesting information regarding INDs, NDAs, ANDAs, sNDAs, discontinued products, and product shortages needed to forecast quota-relevant drug substance needs. The consult request to the Office of Biostatistics will also include a request for forecast needs for the current year and upcoming year.
- Request data on cannabis production from the National Institute on Drug Abuse (NIDA) and any subsequent DEA registrants producing cannabis.
- Request data on the use of methadone in Opioid Treatment Programs from the Substance Abuse and Mental Health Services Administration (SAMHSA).
- Collate data received and prepare usage estimates for quota-relevant drug substances for the coming year.
- Analyze drug usage, incidences of drug shortage, significant regulatory actions, forecasts of future needs, and other data received from FDA offices and other government sources. Identify current developments in the areas of drug shortages, approvals, manufacturing, and regulatory actions that may affect availability, thus requiring quota adjustments.
- Prepare an annual report letter summarizing usage and shortage data, prescribing trends and forecasts of future needs for quota-relevant drug substances, and forward the letter to the DEA.

2. The Office of New Drugs (OND) Review Divisions will:

- Respond to CSS requests for information on INDs, NDAs, sNDAs, discontinued products, and product shortages for quota-relevant drug substances received for the reporting year.

3. The Office of Generic Drugs (OGD) will:

- Respond to CSS requests for information on ANDAs, discontinued products, and product shortages for quota-relevant drug substances received for the reporting year.

4. The Office of the Center Director, Drug Shortage Staff (DSS) will:

- Respond to CSS requests for information on product shortages for quota-relevant drug substances received for the reporting year.

5. The Office of Surveillance and Epidemiology (OSE) will:

- Provide to CSS and the Office of Biostatistics drug sales distribution data (in kilograms) of selected drug substances sold from wholesale distributors and manufacturers to retail and non-retail pharmacy channels. These data are obtained from proprietary databases available to the Agency under contract.

- Include a list of drugs (e.g., List I chemicals) in their review for which data are not available and cannot be provided for the analysis performed by the Office of Biostatistics.

6. The Office of Biostatistics will:

- Utilize statistical models for the annual forecasts and develop/refine modeling approaches as needed.
- Analyze data provided by OSE for quota-relevant drug substances for which data is available to establish trends and forecast future needs.
- Provide forecasted drug needs for quota-relevant drug substances for the current reporting year and upcoming year in tabular form to CSS and work with CSS in generating the final report.

PROCEDURES

1. CSS Procedures
    a. The official request for the annual quota report will generally arrive from DEA in late January, requesting a response from FDA by April 1. To give the consulted groups the most time to prepare their responses, it is recommended that CSS contact DEA in December prior to receiving the official letter to request the list of substances for which DEA will be requesting reporting, in order to begin consult preparation.

    b. Prepare consults for all required groups, requesting information regarding INDs, NDAs, ANDAs, sNDAs, discontinued products, and product shortages needed to forecast quota-relevant drug substance needs.

    c. Send the consults by late December, typically no later than December 30th, and request a due date within 60 days, typically by February 28th. Note that the Office of Biostatistics will typically request a due date that is two to four weeks later than when OSE's drug utilization data become available to them.

    d. Send the consults via email to the designee for the consulted group [usually the Chief Project Manager or designated project manager for consults for the FDA Division or Office, or a pre-determined contact for outside Centers or Agencies].

    e. Compile the consult responses for all groups except OSE and the Office of Biostatistics, and add relevant information into the template letter using narratives or data tables, as appropriate.

f. Once the data from the Office of Biostatistics is received, e.g., as a PDF report with attached Excel spreadsheet, calculate the percent change between each year sequentially. Present the usage data for each substance or drug as a table, including: year 1, year 2, percent change year 1 to 2, year 3, percent change year 2 to 3, etc. For example:

SUBSTANCE	2014 Observed	2015 Observed (%CHANGE)[1]	2016 Observed (%CHANGE)[2]	2017 Observed (%CHANGE)[3]	2018 Observed (%CHANGE)[4]	2019 Observed (%CHANGE)[5]	2020 Predicted (%CHANGE)[7]	2021 Predicted (%CHANGE)[7]

g. Route the letter for clearance to the CSS Director, the Associate Director for Controlled Substances, and the CDER Deputy Director for Regulatory Programs.

h. The final letter is signed by the CSS Director and the CDER Deputy Director for Regulatory Programs.

2. OND Divisions, OSE, Office of Biostatistics, DSS, and OGD Procedures
   a. Upon receipt of the consult from CSS, notify CSS of the designated individual assigned to respond to the CSS request for information.
   b. Notify CSS of any expected or unexpected delays that will impact providing a response by the requested due date.
   c. Respond to the request for information in the consult by the requested due date.

REFERENCES

1. Controlled Substances Act (CSA) of 1970, as amended (primarily 21 U.S.C. 812 and 826)
2. 21 Code of Federal Regulations (CFR) Part 1300
3. Public Health Service Act (PHSA), Title 42 U.S.C. 242 (a)

DEFINITIONS

- **Schedule I Substances and Drugs:** Drugs with high abuse potential and no accepted medical use in the United States. Examples of schedule I drugs are heroin, marijuana, lysergic acid diethylamide (LSD), and methaqualone. A complete list of current schedule I substances and drugs maintained by the DEA can be found on the Internet at http://www.deadiversion.usdoj.gov/21cfr/cfr/1308/1308_11.htm.

- **Schedule II Drugs:** Drugs with high abuse potential and an accepted medical use in the United States. Examples of schedule II drugs include morphine, methadone, oxycodone, hydrocodone, amphetamine, methylphenidate and pentobarbital. A complete list of current schedule II drugs maintained by the DEA can be found on the Internet at http://www.deadiversion.usdoj.gov/21cfr/cfr/1308/1308_12.htm.

- **List I Chemicals:** Chemicals that are used in the manufacture of controlled substances and are important to the manufacture of the substances, as defined in 21 CFR 1300.2. Some examples are ephedrine and phenylpropanolamine, which can be used to manufacture methamphetamine.

- **Quotas:** The quantities of schedule I and schedule II substances and drugs that DEA allows pharmaceutical companies to manufacture or procure each year, as permitted by the CSA.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
05/08/03	N/A	Initial
12/21/20	1	1. MAPP 4200.2 was converted into the current template. 2. Office of New Drugs and Office of Generic Drugs responsibilities were separated. 3. The Drug Shortages Staff responsibilities were added. 4. Language under responsibilities for all groups was revised to reflect current practices. 5. Added a Procedures section.