



General Government Division

B-259550

January 18, 1995

The Honorable F. James Sensenbrenner, Jr.
House of Representatives

Dear Mr. Sensenbrenner:

This correspondence responds to your request for information on how certain controlled substances are regulated, particularly methylphenidate--a central nervous system stimulant approved for the treatment of attention deficit disorder and narcolepsy. The Controlled Substances Act of 1970¹ requires the Attorney General to establish annual production quotas for schedules I and II controlled substances such as methylphenidate to avoid their overproduction and diversion to illegitimate channels while ensuring that legitimate needs are satisfied. Authority for setting these quotas has been delegated to the Deputy Administrator of the Department of Justice's (DOJ) Drug Enforcement Administration (DEA).

The Controlled Substances Act of 1970 established five controlled substance schedules, with schedule I substances being the most strictly regulated. Schedule II controlled substances are considered to have an acceptable medical use in the United States as well as a high potential for abuse that may lead to severe psychological or physical dependence. The controlled substances in these schedules are subject to yearly quota limitations.

There are various quotas for controlled substances, including aggregate production quotas and manufacturing quotas. Aggregate production quotas are the total quantity of a substance that may be produced during a calendar year and are to be proposed and established through Federal Register notices.² Manufacturing quotas are the quantity of a substance that a company can manufacture in a calendar year. Each manufacturer is to be notified in writing of its

¹P.L. 91-513 (1970).

²Before February 1994, these notices had to be reviewed and approved by DOJ's Office of Policy Development (OPD) and the Office of Management and Budget (OMB) prior to publication.

manufacturing quota. Except where noted, this report refers to the aggregate production quota simply as quota.

You asked us to examine, for methylphenidate and other schedule II controlled substances, (1) DEA's methodology for establishing aggregate production quotas and (2) the extent to which DEA's initial and revised established quotas match. In addition, you asked us to examine DEA's compliance with recommendations of an administrative law judge's decision regarding methylphenidate and whether DEA considered and/or used emergency authority³ to address a concern about a possible methylphenidate shortage.

In October 1994, an advocacy group, Children and Adults with Attention Deficit Disorder, and the American Academy of Neurology petitioned DEA to undertake a review to reschedule methylphenidate so that it would no longer be subjected to annual quotas. DEA has accepted the petition for review.

RESULTS

DEA's methodology for establishing aggregate production and manufacturing quotas includes analyzing data provided by pharmaceutical companies and the Department of Health and Human Services (HHS) on past sales, inventories, anticipated need, and market trends. Quotas are set on an annual basis. This involves proposing and establishing initial quotas before the year starts. After the year begins, quota amounts are reassessed on the basis of updated information and revisions can be proposed and established. These amounts are published in the Federal Register, and public comment is solicited throughout this process. Pharmaceutical companies are to be notified in writing of their manufacturing quotas and can request quota adjustments by providing DEA with information such as updated medical-use and sales data.

Although DEA officials generally do not track the extent to which initial and revised aggregate production quotas match, our analysis showed that quotas for many schedule II controlled substances were revised each year between 1990 and 1994.

The 1986 quotas for methylphenidate were the subject of an administrative proceeding. In 1988, a DEA administrative law judge ruled that the method DEA used then to calculate the 1986 methylphenidate quota failed to provide for the country's legitimate medical need. The judge made several recommendations.

³The only authority available to DEA to expedite the quota setting process is found in the Administrative Procedure Act (5 U.S.C. 551, 553(b)(3)(B)).

Although these recommendations were nonbinding, the DEA Administrator accepted most of them and ordered agency officials to, among other things, recalculate the 1986 methylphenidate aggregate production quota and manufacturing quotas and permit the pharmaceutical companies to produce those amounts without lowering the quota level for the year in which the adjustments were made. Our review has shown that DEA has complied with the Administrator's order.

DEA has no emergency authority under the Controlled Substances Act to dispense with the notice and comment provisions of the Administrative Procedure Act. However, under the Administrative Procedure Act, DEA can issue interim rules that make quotas effective upon publication. Because of a 2-month delay in publishing the proposed revised 1993 quotas for several controlled substances, there were concerns about an impending methylphenidate shortage. According to DEA officials, they were aware of the time it was taking to approve the notice and frequently checked on the status of the matter. These officials said they gave no consideration to using the interim rule to establish quotas.

Enclosure I discusses DEA's methodology for establishing quotas. Enclosure II discusses DEA's schedule II quotas and applicable revisions for calendar years 1990 through 1994. Enclosure III discusses DEA's compliance with the administrative law judge's decision concerning the 1986 methylphenidate quotas. Enclosure IV discusses the emergency procedure available to DEA to deal with quota shortages.

APPROACH

To address the issues and concerns in the request, we interviewed DEA, OPD, and Food and Drug Administration (FDA) officials as well as representatives of the two primary methylphenidate manufacturers--Ciba-Geigy Corporation and MD Pharmaceutical, Inc. We also interviewed an official of Children and Adults with Attention Deficit Disorder, a public advocacy group.

We conducted a literature search to obtain information on methylphenidate shortages, reviewed DEA documents used to establish methylphenidate quotas, and reviewed Federal Register quota notices for all schedule II controlled substances for quota years 1990 through 1994. We also compared initial aggregate production quotas with their revised quotas to determine the frequency of quota revisions for all schedule II substances.

As agreed, unless you publicly announce its contents earlier, we plan no further distribution of this correspondence until 10 days after its issue date. At that time, we will send copies to the Attorney General, the Administrator of DEA, and other interested parties. Copies will also be made available to others upon request.

This work was performed under the direction of Weldon McPhail, Assistant Director, with assistance from George Cullen, Evaluator-in-Charge; Kathleen H. Ebert, Senior Evaluator; Patricia Scanlon, Evaluator; and Ann H. Finley, Senior Attorney. If you need additional information, please contact me on (202) 512-8777.

Sincerely yours



Norman J. Rabkin
Director, Administration
of Justice Issues

DEA'S METHODOLOGY FOR ESTABLISHING SCHEDULE II
CONTROLLED SUBSTANCE QUOTAS

The Controlled Substances Act of 1970, P.L. 91-513, 21 U.S.C. 801, et seq., regulates the manufacture and distribution of controlled substances such as narcotics, stimulants, depressants, and hallucinogens. The act (1) established five schedules to classify controlled substances on the basis of accepted medical use, potential for abuse, and safety or potential for dependence and (2) provided mechanisms for controlling substances, adding substances to the schedules, reclassifying substances between schedules, and removing substances from control. The act requires the Attorney General to establish annual production and manufacturing quotas of schedules I (the most restrictive category) and II controlled substances. The responsibility for setting quotas has been delegated to the DEA Deputy Administrator.

DEA's methodology for establishing aggregate production quotas and manufacturing quotas includes analyzing data on past sales, inventories, and anticipated need. DEA is to set quotas annually. Initial quotas are to be established in late fall of the preceding year. For example, 1994 quotas were set in the fall of 1993. DEA's methodology is to obtain the following information from pharmaceutical companies: actual sales data from the previous year, estimated sales data for the current year, estimates of the next year's net disposals,⁴ and estimates of year-end inventories for the current year. DEA uses these data to calculate aggregate production quotas.

After making its calculations, DEA is to propose initial aggregate production quotas in a Federal Register notice for public comment.⁵ After considering all comments, DEA is to issue a final order establishing initial quotas. Pharmaceutical companies are then to be notified in writing of their established initial manufacturing quotas.⁶

⁴Net disposals are the total quantity of a controlled substance used, sold, or otherwise disposed of by a company.

⁵In 1993, DEA was required to submit quota notices to OPD and OMB for review and approval before having them published in the Federal Register. Since early 1994, DEA's Deputy Administrator approves the quotas for publication in the Federal Register and provides a courtesy copy to OPD and OMB.

⁶Regulations require that this activity occur before the calendar year starts for which the quotas apply.

After the calendar year starts, pharmaceutical companies are to provide DEA with sales and inventory data from the previous year. On the basis of this updated information, DEA is to review the previously established initial production quotas and propose to revise them if necessary. For example, the 1994 established initial quota for methylphenidate was revised following a consideration of

- actual 1993 year-end sales data;
- actual 1993 year-end inventory data;
- FDA estimates of U.S. medical needs; and
- other factors, such as manufacturing problems, losses, or employee strikes that could affect manufacturing capability.

Next, proposed revised quotas are to be published in a Federal Register notice. As with the initial quotas, DEA is to consider public comments and publish the revised quotas in a final order. Pharmaceutical companies are then to be notified in writing of their revised manufacturing quotas. In addition, a pharmaceutical company can request an increase to its manufacturing quota at any time by submitting such information as updated sales data to DEA. Manufacturing quotas can be increased only to the level that they do not exceed the aggregate production quota. If necessary, DEA can increase an established aggregate production quota on the basis of the supporting data to meet changing needs.

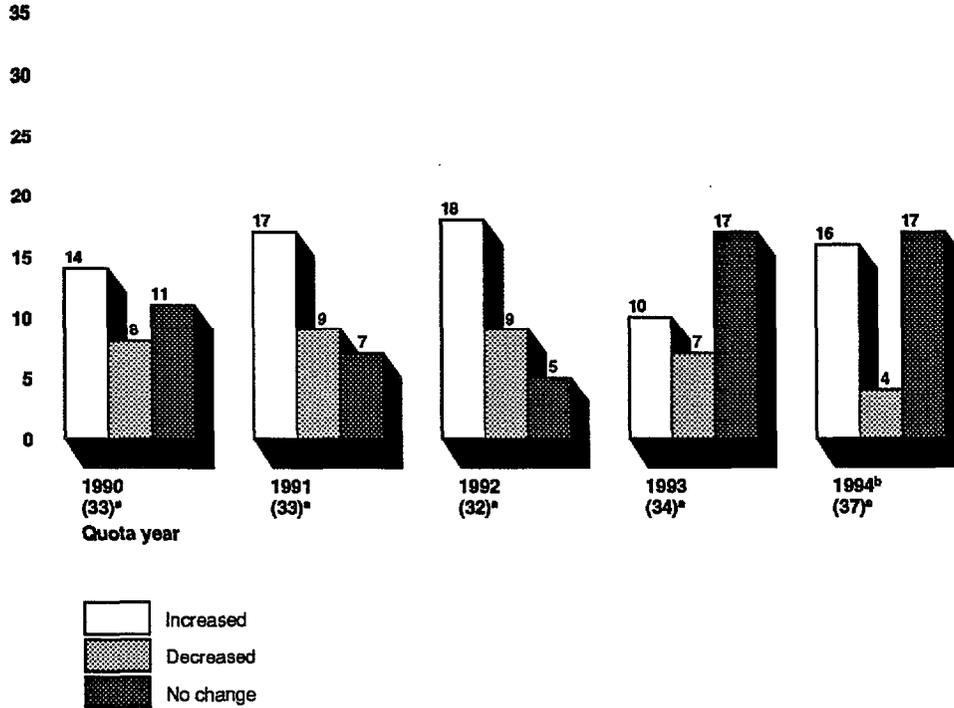
DEA REVIEWS AND REVISES QUOTAS
TO ENSURE ADEQUATE SUPPLY

According to a DEA official, DEA does not generally track differences between initial and revised aggregate production quotas. Rather, quotas are to be reviewed and revised to ensure their adequate supply for legitimate needs while seeking to avoid diversion for illicit purposes. Further, DEA officials said that they had found revising quotas after the start of the calendar year to be an effective method for controlling production because the most recent year-end sales and inventory data are available at that time. In addition, FDA submits its evaluation of medical and scientific requirements based on updated sales information from surveys covering about 80 percent of all drug outlets.

Our analysis of schedule II initial and revised established aggregate production quotas for 1990 through 1994 indicates that quotas for many substances were revised during each year. (See figure II.1.) For example, in 1990, quotas for 22 of 33 schedule II controlled substances were revised. In 1994, quotas for 20 of 37 schedule II controlled substances were revised. With few exceptions, the quotas for schedule II controlled substances were revised at least once over the 5-year period.

Figure II.1: The Extent to Which Revised Established Quotas Increased, Decreased, or Did Not Change From Initial Established Quotas for Schedule II Controlled Substances, 1990-1994

40 Number of schedule II controlled substances



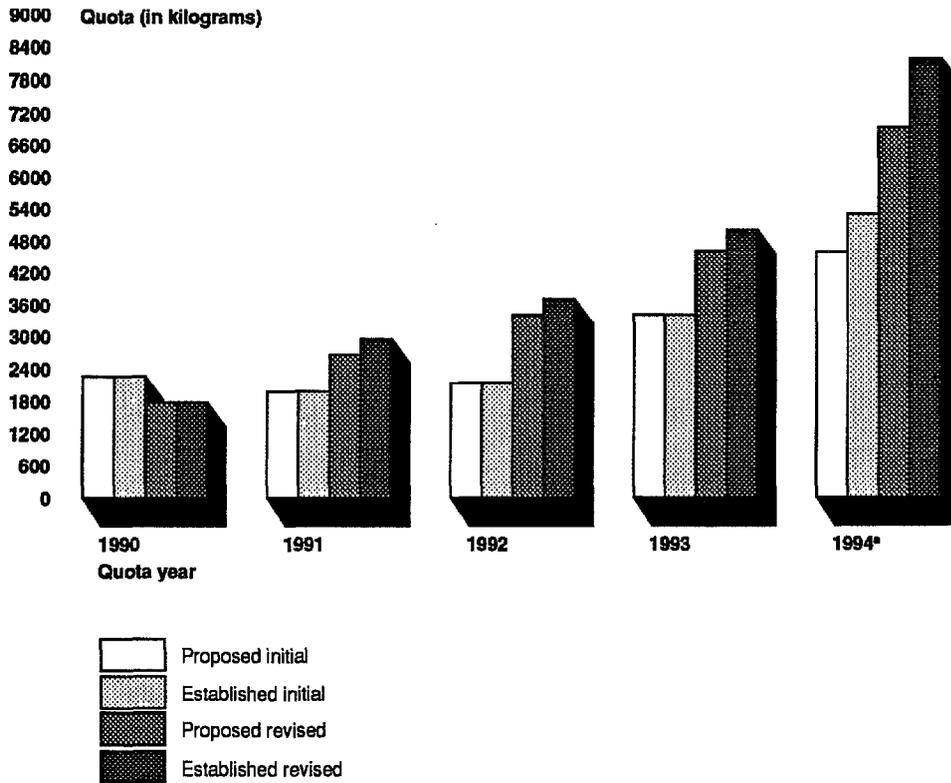
^aTotal number of schedule II controlled substances for the year.

^bAs of November 1, 1994.

Source: Federal Register.

In particular, methylphenidate's revised quota increased each year except 1990. (See figure II.2.) In 1994, the quota increased almost 55 percent, from an established initial quota of 5,300 kilograms to an established revised quota of 8,189 kilograms (as of November 1994).

Figure II.2: Methylphenidate Quotas, 1990-1994



*After issuing the 1994 established revised quota for methylphenidate of 7,313 kilograms in June 1994, DEA increased this quota to 8,189 kilograms in September 1994.

Source: Federal Register.

DEA'S COMPLIANCE WITH THE ADMINISTRATIVE
PROCEEDING REGARDING METHYLPHENIDATE

In October 1985, DEA published a notice in the Federal Register proposing the initial 1986 methylphenidate aggregate production quota. Both Ciba-Geigy Corporation and MD Pharmaceutical, Inc., submitted objections and requested hearings on the proposed quota. The 1986 methylphenidate aggregate production quota and manufacturing quotas and DEA's net disposal estimates for methylphenidate were the subject of an administrative proceeding. This proceeding was generally governed by the procedures set forth in the Administrative Procedure Act (5 U.S.C. 551-559). The administrative law judge submitted his opinion and recommendations to the DEA Administrator on April 29, 1988. These were not binding on the DEA Administrator. The Administrator, after reviewing the entire record, made a final decision and issued a final rule accepting most of the judge's recommendations.

ADMINISTRATIVE LAW JUDGE'S
FINDINGS AND RECOMMENDATIONS

The administrative law judge had findings and made recommendations in four issues:

- The judge found that the 1986 aggregate production quota and manufacturing quotas for methylphenidate were not calculated so as to provide for the legitimate medical need for this substance and for the other purposes specified in the statute. He recommended that DEA recalculate the quotas.
- The judge found that DEA's quota setting procedures in place were inappropriate and insufficient to enable the agency to fulfill its statutory obligation. The judge recommended that DEA develop new procedures.
- The judge recommended that the 1987 quotas be adjusted, if necessary, to bring the stocks of methylphenidate to the levels at which they would have been had the 1986 quotas been computed in accordance with the law.
- The judge found that the setting of disposal quotas was unlawful and recommended that if DEA should desire to continue employing disposal quotas, it should use rule-making procedures to do so.

DEA ADMINISTRATOR'S
DECISION AND FINAL ORDER

On December 16, 1988, the Administrator published in the Federal Register a final rule in which he ordered the DEA staff to redetermine the 1986 aggregate production quota in order to fulfill the statutory obligation to establish quotas that provide for the medical, scientific research, and industrial needs of the United States, as well as for the other purposes specified in the statute. In addition, the Administrator ordered DEA officials to

- recalculate the 1986 methylphenidate quotas and permit the pharmaceutical companies to produce those amounts without lowering the quota level for the year in which the adjustments were made;
- discontinue using disposal quotas until the need for such allocations arise and they have been subjected to the proper rule-making procedures;
- increase the relative size of the quota assigned to generic methylphenidate; and
- use the most reliable data and information available for setting future quotas for methylphenidate before the start of that calendar year.

The Administrator did not accept the administrative law judge's finding that DEA's quota setting procedures were inappropriate and insufficient to enable the agency to fulfill its statutory obligation.

DEA has complied with this order. The March 2, 1989, Federal Register notice recalculated the 1986 methylphenidate quota. We reviewed DEA's policies, procedures, and documents used for setting quotas for 1990 through 1994 and obtained DEA's comments verifying that the agency does not use disposal quotas and that the relative size of the quota assigned to generic methylphenidate increased. We also interviewed DEA and FDA officials who said that DEA uses the most reliable data and information available at the time for setting quotas.

DEA'S AUTHORITY FOR
ADDRESSING QUOTA SHORTAGES

In accordance with the Controlled Substances Act, DEA establishes controlled substance quotas. DEA is to follow the procedures in the Administrative Procedure Act⁷ in establishing the quotas. DEA has no emergency authority under the Controlled Substances Act to dispense with the notice and comment provisions of the Administrative Procedures Act. However, under the "good cause" provision of the Administrative Procedure Act, DEA can issue interim rules on quotas before the required public notice and comment period.⁸ When an interim rule is implemented, the quota becomes effective upon publication in the Federal Register. Afterwards, interested parties can file comments and the interim rule is ultimately adopted with or without change based on any comments received.

DELAY IN APPROVING THE 1993
PROPOSED REVISED QUOTAS

In 1993, all of DEA's quota regulations had to be reviewed and approved by OPD and OMB before publication in the Federal Register. Because OPD misplaced the paperwork for several controlled substances, including methylphenidate, during the review process, there was a 2-month delay in publishing the proposed revised quotas for these substances. As a result, there were reports of an impending methylphenidate shortage. With DEA's intervention, OPD found the notice, the review and approval process resumed, and the revised quotas were finally published in the October 7, 1993, Federal Register.

DEA officials said they were concerned about the time it was taking to approve this notice and frequently contacted OPD about the notice's status. DEA officials advised us that they gave no consideration to using the interim rule to establish the quotas. In retrospect, DEA's Associate Chief Counsel said it would have been within DEA's power to issue an interim rule to set quotas. However, in their view, using an interim rule would not have alleviated the delay because any proposed quotas, even under the emergency authority, would have had to be reviewed and approved by OPD and OMB before publication in the Federal Register.

⁷5 U.S.C. 551, et seq.

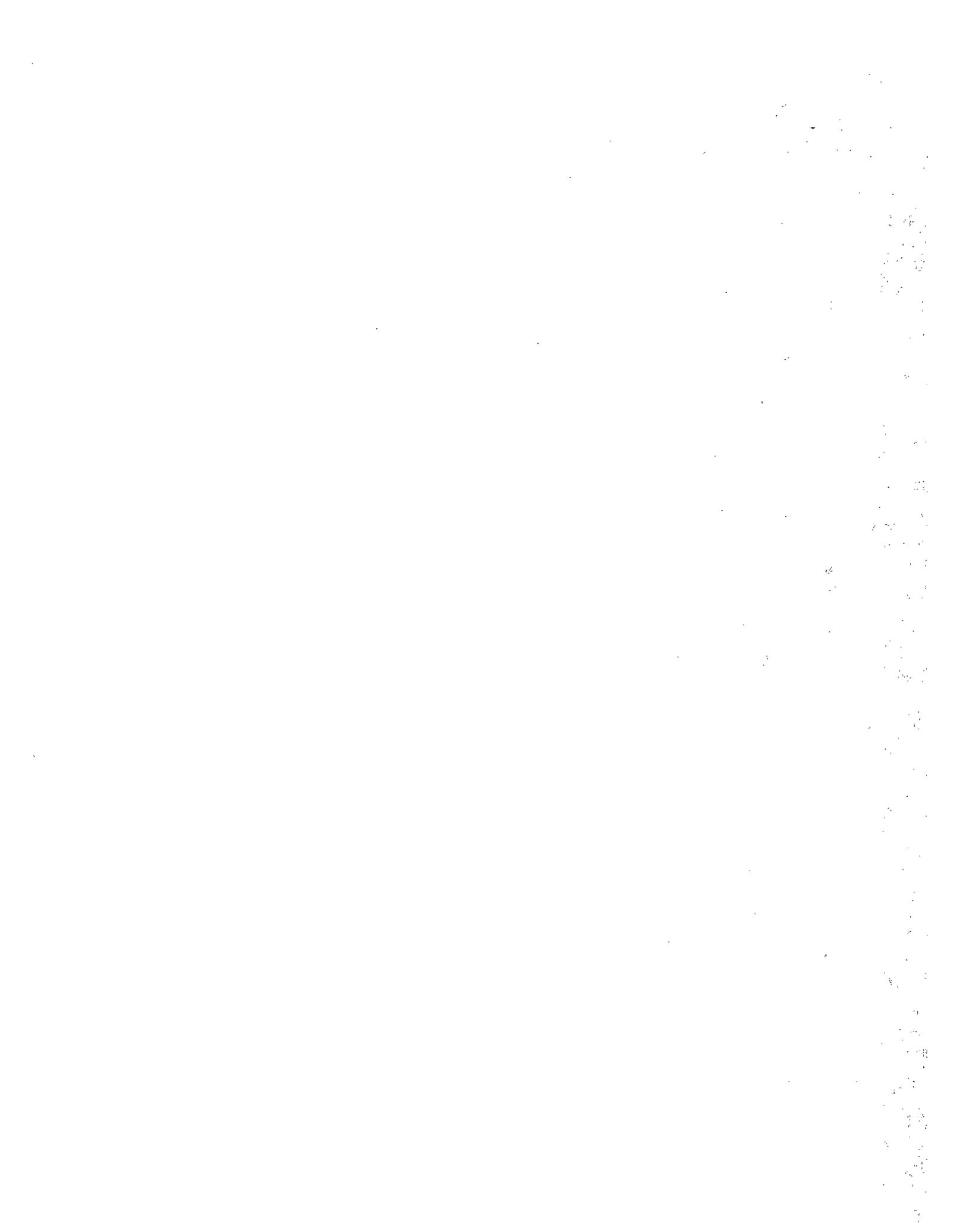
⁸DEA can dispense with the notice and comment procedures when these procedures would be impracticable, unnecessary, or contrary to the public interest.

Before this delay, the DEA Administrator had written to the Deputy Attorney General seeking alternatives to the review and approval process of Federal Register notices for controlled substance quotas because of the time it required. In his view, the lengthiness of this process could cause production delays, ultimately affecting supply.

STREAMLINING THE
QUOTA REVIEW PROCESS

In February 1994, OMB declared DEA quota regulations to be exempt from OMB centralized review. According to DEA officials, this decision also exempted them from OPD review and approval. Under this new procedure, once the DEA Deputy Administrator approves either proposed or final quota notices, they are to be forwarded to the Federal Register for publication. For example, the DEA Administrator approved the 1994 proposed revised quotas on April 5, 1994, and then forwarded them to the Federal Register, which published them on April 13. The revised quotas were published on June 22, 1994, and the two pharmaceutical companies received their manufacturing quotas. Thus, DEA officials contend that delays such as the one that occurred in 1993 should not be repeated in the future. Since this new procedure was implemented, DEA used an interim rule in September 1994 to increase the methylphenidate quota to meet the medical needs of the country.

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