1996. In order to assure consideration by the agency, comments are to be filed by that date.

Elsewhere in this issue of the Federal Register, the agency is publishing two graphs that were inadvertently omitted from the appendix to the notice. The appendix did not appear in the Federal Register on August 11, 1995, but can be purchased from the Government Printing Office (stock number 017012003737).

Interested persons may, on or before December 28, 1995, submit to the Dockets Management Branch (address above) written comments regarding this notice. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 11, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–25671 Filed 10–12–95; 1:38 pm]

BILLING CODE 4160–01–F

[Docket No. 95N–0253J]

Analysis Regarding the Food and Drug Administration's Jurisdiction Over Nicotine-Containing Cigarettes and Smokeless Tobacco Products; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document entitled ''Nicotine In Cigarettes And Smokeless Tobacco Products Is A Drug And These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act'' that appeared in the Federal Register of August 11, 1994 (60 FR 41453). The document was published with some typograpical errors. In addition, the document announced the availability of appendices. The agency has discovered that it inadvertently omitted two diagrams from the appendices. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION: In FR Doc. 95–20052, appearing on page 41453 in the Federal Register of Friday, August 11, 1995, the following corrections are made:

1. On page 41453, in the 2d column, under the **ADDRESSES** caption, in line 7, the word ''the'' is added before the word ''Superintendent''; and in the 3d column, under the **SUPPLEMENTARY INFORMATION** caption, in the 2d full paragraph, in line 3, the word ''of'' is corrected to read ''on''.

2. In the appendices which were made available by the agency through the Superintendent of Documents, Government Printing Office, on pages A–80 and A–81 the following illustrations are added:

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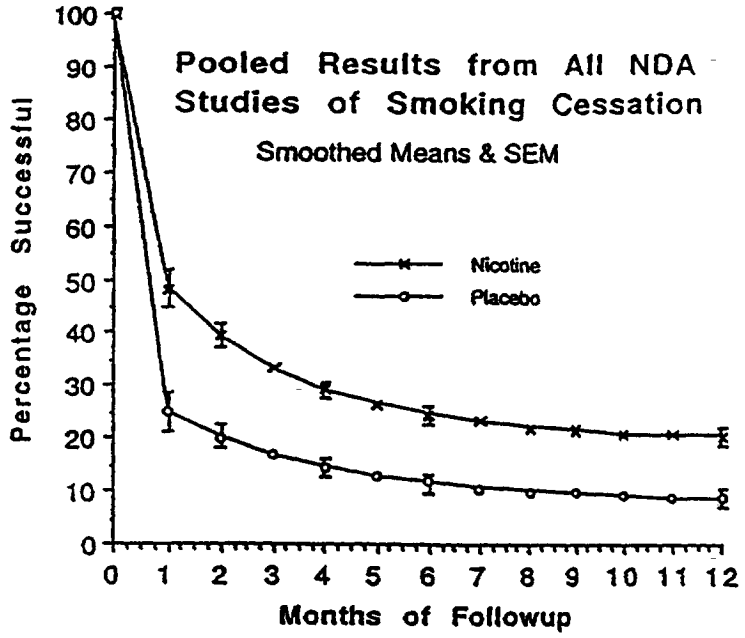
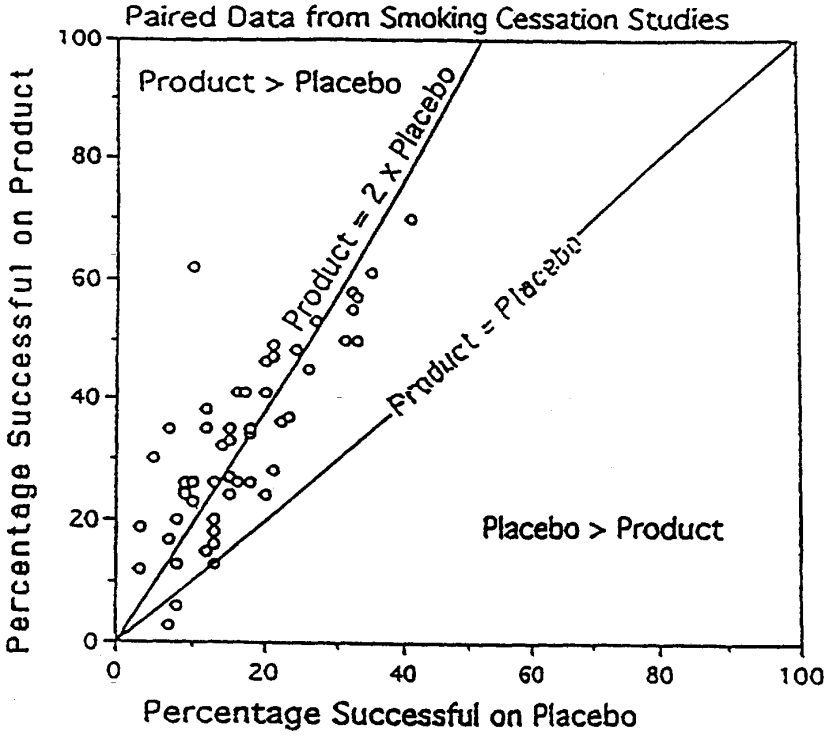
Plotting the data :



There appears to be a pattern in the data, such that the quit rate in the nicotine group is about twice the quit rate in the placebo group. Plotting the quit rates for each time point in each study in this fashion (placebo on x-axis, nicotine on y-axis):



Discussion

The consistency of NDA data shows the difficulty of smoking cessation, even for committed adults who decide to seek medical help in quitting. The data also reveal the widespread importance of nicotine's CNS effects in smoking by illustrating the efficacy of nicotine delivery systems (including "tasteless" transdermal systems) in helping people reduce or quit smoking--at least while using smoking cessation products. For this population of male and female, pack-a-day, typical smokers aged 20-50, nicotine replacement products reliably improved their ability both to stop smoking and to remain abstinent from cigarettes. Smokers using products that delivered about 14-24 mg/day of nicotine had an initial quit rate of about

Dated: October 11, 1995.
William B. Schultz,
Deputy Commissioner for Policy.
[FR Doc. 95–25669 Filed 10–12–95; 1:38 pm]
BILLING CODE 4160–01–C

[Docket No. 95D–0283]

Deciding When To Submit a 510(k) for a Change to an Existing Device; Draft Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of an August 1, 1995, draft guidance entitled ''Deciding When to Submit a 510(k) for a Change to an Existing Device.'' The draft guidance includes a flowchart model that can be used by manufacturers in their decisionmaking to analyze whether certain changes in a device could significantly affect the safety or effectiveness of the device and, therefore, require submission of a new 510(k). The draft guidance is intended to provide direction to manufacturers, specification developers, and distributors of devices who intend to modify their device and are in the process of deciding whether the modification requires a new premarket notification submission (510(k)).

DATES: Written comments by December 15, 1995.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Deciding When to Submit a 510(k) for a Change to an Existing Device'' to the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597 (outside MD 1–800–638–2041). Send two self-addressed adhesive labels to assist that office in processing your requests, or FAX your request to 301–443–8818. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Copies of a facsimile of the draft guidance, are available from the Division of Small Manufacturers Assistance (DSMA) Facts on Demand, Center for Devices and Radiological Health (CDRH), 1–800–899–0381. Copies of the draft guidance may also be obtained from the electronic docket administered by DSMA and are available to anyone with a video terminal or personal computer (1–800–252–1366).

FOR FURTHER INFORMATION CONTACT: Harvey Rudolph, Center for Devices and Radiological Health (HFZ–100), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–2444.

SUPPLEMENTARY INFORMATION:

I. Background

On April 8, 1994, FDA circulated for comment the first draft guidance entitled ''Deciding When to Submit a 510(k) for a Change to an Existing Device.'' The draft guidance was intended to provide direction to manufacturers on deciding when to submit a new 510(k) for changes to an existing device. The April 8, 1994, draft guidance was the subject of a May 12, 1994, FDA teleconference. The April 8, 1994, draft guidance was also the subject of discussion at several trade and industry association meetings.

FDA received over 60 comments regarding the April 8, 1994, draft guidance. Based on the comments received, FDA developed an August 1, 1995, second draft guidance entitled ''Deciding When to Submit a 510(k) for a Change to an Existing Device.'' FDA is now announcing the availability of the August 1, 1995, draft guidance to elicit further public comment.

II. When to Submit a 510(k) for a Change to an Existing Device

Whenever a manufacturer of a legally marketed device decides to change the device's design or labeling, it is faced with a decision on whether to submit a 510(k). Section 807.81(a)(3) (21 CFR 807.81(a)(3)) states that a premarket notification is required for changes to a currently marketed device that ''could significantly affect the safety or effectiveness of the device.'' FDA staff have tried to define this phrase with greater accuracy, as well as the criteria contained in 21 CFR 807.81(a)(3)(i) and (ii) which are expressed in general terms using adjectives such as ''major'' and ''significant,'' because they can sometimes lead to subjective interpretation.

FDA's previous attempts to develop guidance in this area have not been entirely successful, and manufacturers have frequently expressed the need for more definitive guidance. FDA has now developed such guidance and is making it available as a draft for public comment.

III. The Draft Guidance

The draft guidance has been developed to provide aid to manufacturers, specification developers, and distributors of class I, class II, or preamendment (devices in commercial distribution before May 28, 1976) class III devices for which premarket approval has not yet been required under section 515(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(b)) who intend to modify their device and are in the process of deciding whether the modification meets the regulatory threshold for submitting a new 510(k). Whenever possible, the draft guidance attempts to incorporate existing guidance and policy regarding when a 510(k) is necessary for modifications to a currently legally-marketed device.

The draft guidance is not intended to supplant existing definitive guidance for modifications to specific devices, i.e., for daily wear contact lenses. Moreover, the draft guidance is not intended to apply to device kits, nor is it intended to apply to combination products, such as drug/device or biologic/device combinations. The draft guidance is also not intended to address the need for submitting a 510(k) by refurbishers or remanufacturers of devices. FDA intends to develop additional guidance specific to these situations.

The types of modifications addressed in the draft guidance include labeling changes, technology or performance specifications changes, and materials changes. The basis for comparison of any changed device is the device described by a cleared 510(k) or a legally marketed pre-1976 device. That is, manufacturers may make a number of changes without having to submit a 510(k), but each time they make a change, the device they should compare it to is their most recently cleared device or their pre-1976 device, not the current legally marketed device. In effect, manufacturers need to submit a new 510(k) only when the sum of the incremental changes, taken together as though they were in fact one change, exceeds the § 807.81(a)(3) threshold, ''could significantly affect the safety or effectiveness of the device.''

According to the draft guidance, because many simultaneous changes may be considered in the evolution of device design, each type of change should be assessed separately and, when any one change leads the manufacturer to decide to submit a 510(k), then a 510(k) incorporating all