Procter&Gamble

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Health Care Research Center
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July 9, 2001 01 JUL 17

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 01D-0192; Draft Guidance for Industry on Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution; Availability

Ladies and Gentlemen:

Procter & Gamble (P&G) respectfully submits the following comments on the draft guidance for industry entitled "Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution"; the notice of the availability of this guidance was published in the *Federal Register* (66, No. 94, 26867-26868, May 15, 2001).

Procter & Gamble recommends that the guidance document state that registrants will receive a copy of a submitted Form FDA 2656 (Registration of Drug Establishment/Labeler Code Assignment), stamped with receipt date, which will verify that the FDA has received the submission and serve as confirmation that the firm is registered. This will occur whether the 2656 is an initial registration, an annual re-registration or a report of changes. P&G also suggests the agency consider providing acknowledgment of receipt of Form FDA 2657 (Drug Product Listing) and Form FDA 2658 (Registered Establishments' Report of Private Label Distributors), both initial and updates.

Once an electronic submission system is in place, it is anticipated that registrants would receive verification of receipt of information electronically. P&G suggests that the agency post the status of submissions on the Internet, which companies could access by use of a password. This would eliminate FDA personnel having to send out e-confirmations. For plant registrations, the agency could add a "Registration (up)date" line to the "Drug Registration and Listing System" and make it available on-line. This list of active domestic and foreign sites, which shows the registration number of a plant, labeler code, name of firm and address and which is currently available through FOI, could then serve as an information source for companies to determine whether all their plants are up-to-date on registrations.

We thank the agency for its consideration of these comments.

Sincerely,

Nancy H. Allen

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Regulatory Affairs

01D-0192

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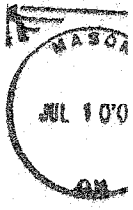

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