

way to ensure the order of submission would be to require all submissions to be made in person, with the establishment of some kind of monitored line. The owner of the FDA-occupied building has given the agency the option of permitting applicants to line up outside the building at 12:01 a.m. on the morning submissions may be accepted. However, such lines would raise issues of security and fairness for applicants and could lead to evidentiary disputes over which applicant, if any, was in line first. FDA is already aware of at least one instance in which an applicant videotaped its arrival on government property in an attempt to document that it was first to submit a patent challenge. Thus, this approach could lead to administrative proceedings and litigation over tie-breaking virtually simultaneous submissions. In addition, such an approach would disadvantage applicants who do not make submissions in person, because mail deliveries are likely to be made to FDA after the door opens for in person submissions.

The agency also considered requiring submission by mail and then date- and time-stamping submissions based on the order they were processed by the mailroom and document room. This approach would require FDA to determine, from among the various submissions made in the same delivery, which submission was first, itself an arbitrary process. Is the first submission the first ANDA to be removed from the mail bag, or the document on top of the pile after the mail is removed from the delivery container?

The agency even considered adopting a lottery approach, in which one ANDA would be chosen at random from among all the eligible ANDAs submitted on the same first day. This approach, although appealing in its simplicity and no less random than mail delivery or an applicant's place in line, has no support in the statute.

Finally, FDA considered permitting submission by facsimile. However, this approach raises many practical concerns involving after-hours submissions, jammed fax machines, and disputes over submission order. In sum, all of these approaches were rejected because they raise safety concerns, are administratively unworkable, or would arbitrarily and unfairly distinguish between similarly situated applicants. In addition, none of them addresses the fundamentally arbitrary nature of declaring any one patent challenge made on a certain day to be previous to all other challenges made on that day.

### *C. 180-Day Exclusivity and Multiple Same Day Patent Challenges*

FDA intends to interpret the phrase "for which a previous application has been submitted" in section 505(j)(4)(B)(iv) of the act to mean an ANDA that has been submitted on a previous day. Thus, when multiple ANDAs containing paragraph IV challenges to patents are submitted to FDA on the same day—and no paragraph IV certification to that patent has been submitted on a previous day—FDA intends to consider none of the patent challenges to be previous to other challenges to the same patent submitted on the same day and all of those challenges as previous to paragraph IV certifications to the same patent submitted on a subsequent day. This is the general interpretation described in the 1999 proposed rule.

Under this approach, all of the applicants submitting substantially complete ANDAs, amendments, or supplements containing a paragraph IV certification for a listed patent on the same first day would be eligible for 180-day exclusivity. That exclusivity would begin to run for all of the applicants eligible for 180-day exclusivity from the earlier of the initial commercial marketing of the drug by any of the first applicants or by a court decision finding the specific patent as to which the applicants were first to file paragraph IV certifications invalid, unenforceable, or not infringed. During the exclusivity period, FDA may approve any other first applicant's ANDA, but no other ANDAs. Any first applicant's ANDA approved after the exclusivity has been triggered will share in the remaining period of exclusivity. Once the 180-day exclusivity period has run, FDA may approve all subsequent ANDAs.

The agency believes that this exclusivity approach is consistent with the statutory language in that, under at least one reasonable reading of section 505(j)(5)(B)(iv) of the act, none of the applications submitted on the same day is "previous" to any other application submitted on the same day, and all applications submitted on the same day are previous to any application submitted on any day thereafter.

This interpretation is also consistent with the intent of both the 180-day exclusivity provision, in particular, and the Hatch-Waxman Amendments, in general. Instead of giving exclusivity to a single applicant who may be first only by dint of jockeying for a better place in line, or by the happenstance of location within a pile of mail, this approach recognizes that all of the applicants who challenged a patent on the first day such

a challenge is submitted challenged the patent at essentially the same time, and rewards them accordingly.

The approach maintains the incentive to be first to submit a patent challenge but, in the case where there are multiple applicants submitting patent challenges on the same first day, it will provide an equal chance at the benefits of exclusivity to all of those applicants. The approach will also provide the opportunity to be the sole beneficiary of exclusivity if an applicant obtains approval of its ANDA and begins to market at least 180 days before any of the other first applicants begins to market.

Finally, this approach will permit applicants to submit ANDAs by U.S. mail, courier, delivery service, or in person on a more reasonable timetable; preserve the safety and security of the applicants and FDA property and staff; and prevent time-consuming disputes over "who's first," which rely on video and other evidence.

This guidance is being issued as a level 1 guidance for immediate implementation, consistent with FDA's good guidance practices regulation (21 CFR 10.115). The agency believes that given the need for public guidance on this pressing issue and existing liability, safety, and security concerns, public comment is neither feasible nor appropriate before implementing this guidance. Comments on the guidance are welcome at any time.

FDA intends to implement this approach immediately for all applicable 180-day exclusivity determinations made by FDA on or after the date of the notice announcing the availability of this guidance (including for patent certifications that were submitted prior to the date of the notice where the exclusivity determination has not yet been made). The approach described in this guidance will remain in effect until superseded. As noted in this section I, to date, FDA's exclusivity decisions have only involved applications or amendments submitted on different days.

This guidance represents the agency's current thinking on 180-day exclusivity when multiple ANDAs are submitted on the same day. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

### **II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic