

Waxman Amendments—to maintain a balance between the rights of the NDA holders and patent owners, and the desire to have more rapid availability of generic drugs. Our revised interpretation of section 505(j)(2)(B)(iii) of the act accomplishes two statutory objectives: (1) It closes a possible loophole that would have allowed ANDA applicants to avoid any 30-month stay and (2) it prevents multiple 30-month stays per ANDA application. A similar conclusion applies to the parallel provisions of section 505(b)(2) of the act.

We based our change in position on a reevaluation of the statutory text and concluded that the act is ambiguous on this issue of multiple 30-month stays. We note that certain other legal interpretations or theories may support a single 30-month stay, but we believe that the position we have taken in the final rule is the most appropriate.

The preamble to the proposed rule explained the rationale for our different interpretation (see 67 FR 65448 at 65454 to 65456). In brief, after reviewing the text of section 505(j)(2)(B)(i) through (iii) of the act, we believe that these provisions may be reasonably interpreted so that notice and the opportunity for a 30-month stay do not flow from all paragraph IV certifications. However, one notice of a paragraph IV certification and one full opportunity for a 30-month stay will always be required. This outcome—the opportunity for one 30-month stay during which patent rights can be litigated, but no multiple 30-month stays per ANDA or 505(b)(2) application to unreasonably delay approvals of competitor drugs—is a reasonable and balanced interpretation of the act.

We disagree with the comments that claimed that notice and 30-month stays are required only for paragraph IV certifications contained in original ANDAs because the notice provision at section 505(j)(2)(B)(ii) references only section 505(j)(2)(B)(i) of the act. This interpretation would eliminate the opportunity for a 30-month stay in any situation where an ANDA applicant waits until an amendment to submit a paragraph IV certification. As we explained in the proposed rule (see 67 FR 65448 at 65455 to 65456), section 505(j)(2)(B)(iii) of the act specifically requires ANDA applicants to give notice if they amend their applications to include their first paragraph IV certification. For these reasons, we do not interpret the act to require that only paragraph IV certifications contained in original ANDA applications will trigger the notice requirements and the possibility of a 30-month stay.

Our interpretation ensures that the NDA holder and patent owner will receive notice of at least one paragraph IV certification and have one full opportunity for a 30-month stay. However, we also disagree that every paragraph IV certification requires notice and an opportunity for a 30-month stay. We will require notice to the NDA holder and patent owner of a later paragraph IV certification if: (1) The ANDA or 505(b)(2) application did not previously contain a paragraph IV certification, but is amended to include a paragraph IV certification; or (2) a previous notice of a paragraph IV certification did not result in one full opportunity for the 30-month stay under the act.

This approach is consistent with the statutory language. By its terms, section 505(j)(2)(B)(i) of the act, and the nearly identical language applicable to 505(b)(2) applicants, requires that the ANDA applicant submitting a paragraph IV certification in its original ANDA “include in the application” that it will provide the required notice. Section 505(j)(2)(B)(ii) of the act sets forth the required content of the notice referred to in clause (i). Under section 505(j)(5)(B)(iii) of the act, we are prohibited from approving an application with a paragraph IV certification if an action has been brought within 45 days of the date the notice under section 505(j)(2)(B)(i) is received. The text of section 505(j)(5)(B)(iii) refers multiple times to “the notice provided [or made] under paragraph (2)(B)(i).” Thus, at a minimum, it cannot be said the statute clearly applies the notice requirement to all paragraph IV certifications, whether in original or amended ANDAs.

By contrast, section 505(j)(2)(B)(iii) of the act refers to amended, not original, ANDAs. It addresses the question of notice when an ANDA is amended to include a paragraph IV certification. Our interpretation eliminates the possibility that an ANDA applicant could evade any notice that could lead to a 30-month stay by omitting any paragraph IV certification in an original ANDA, and then later amending the application to include such a certification. By providing one full opportunity for the 30-month stay, we reduce the opportunity for intentional manipulation of the filing of paragraph IV certifications.

We do not agree that the act’s language governing the operation of paragraph IV certifications, notice, and 30-month stays is clear and unambiguous. As the multiple interpretations advanced by the comments demonstrate, the statutory

language may plausibly be read in different ways. It is certainly reasonable to interpret “include” as used in the act to mean “contain.” That is the meaning we understood the word to have when we issued the proposed rule (see 67 FR 65448 at 65455). Thus, it is a reasonable construction of the act to conclude that when an application is amended to contain a paragraph IV certification (when it did not previously contain such a certification), it is thus amended to include such a certification; and, that once an application contains such a certification, adding a new one does not amend or change the application to include or contain one, since it already contained such a certification. In any event, reliance on words in isolation is misplaced. As Judge Learned Hand observed, “Words are not pebbles in alien juxtaposition; they have only a communal existence; and not only does the meaning of each interpenetrate the other, but all in their aggregate take their purport from the setting in which they are used \* \* \*.” *NLRB v. Federbush Co.*, 121 F.2d 954, 957 (2d Cir. 1941). Our interpretation of the 30-month stay provision is fully consistent with this principle.

We also reject the view that our interpretation of the statutory language “amended to include” is inconsistent with the use of the word “include” elsewhere in the statute. We do not agree that the use of “include” in section 505(j)(7)(A)(ii) and (j)(7)(A)(iii) of the act cannot be squared with our interpretation of that term in section 505(j)(2)(B)(iii) of the act. Sections 505(j)(7)(A)(ii) and (j)(7)(A)(iii) of the act, which relate to updating the Orange Book every 30 days to take into account drug approvals and patent listings, provide that the Secretary “shall revise the list to include each drug which has been approved \* \* \* during the [intervening] thirty-day period” and when that updated drug information is recorded, “in revisions made under clause (ii), [shall] include such [patent] information for such drug.” That language requires publication of revisions to include something that was not previously contained in the Orange Book, i.e., approved drugs and patents that were not listed in the version of the Orange Book that existed immediately before the amendments were filed. The Secretary would publish nothing, under this statutory directive, if in the preceding 30 days, no new drugs were approved or patent listings filed. Similarly, when an ANDA or 505(b)(2) application is amended to include a paragraph IV certification, when no such certification is contained in the