

conjunction with our general rulemaking authority in section 701(a) (21 U.S.C. 371) of the act. Section 505(b) and (c) of the act describes the contents of an NDA and 505(b)(2) application, including the patent submission and patent certification requirements. Section 505(j) of the act describes the contents of an ANDA, including patent certification requirements. Sections 505(b)(2)(A) and 505(j)(2)(A)(vii) of the act, respectively, require patent certifications, while sections 505(b)(3) and 505(j)(2)(B) of the act require those applicants who have made a paragraph IV certification to provide notice to the NDA holder and patent owner.

The final rule clarifies the types of patents which NDA applicants and NDA holders must and must not submit to FDA for listing in the Orange Book. It also requires a more detailed patent declaration from NDA applicants and NDA holders or patent owners using declaration forms. The specific legal authority for each provision is set forth in the preamble discussion accompanying it.

For ANDA and 505(b)(2) applicants, the final rule reduces the number of notifications sent to patent owners and NDA holders. The specific legal authority for this action is set forth in the preamble discussion of our changed interpretation.

VI. Environmental Impact

We have determined under 21 CFR 25.30(h) and 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on

the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Executive Order 13132: Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that this final rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have concluded that the final rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VIII. Paperwork Reduction Act of 1995

This final rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). We describe these provisions below in this section of the document with an estimate of the annual reporting burden. Our estimate includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed

Description: The final rule clarifies the types of patent information that must and must not be submitted to FDA as part of an NDA, an amendment or supplement. The final rule also requires persons submitting an NDA, amendment or supplement, or submitting information on a patent after NDA approval, to make a detailed patent declaration using required FDA declaration forms. The final rule permits the possibility of only one 30-month stay per each ANDA or 505(b)(2) application's approval date in the event of patent infringement litigation because the final rule does not require ANDA or 505(b)(2) applicants to provide a notice of certification of invalidity or noninfringement of a patent if the application already contains such a certification or if a full opportunity for a 30-month stay resulted after such notice.

Description of Respondents: Persons submitting an NDA, amendment or supplement, or submitting information on a patent after NDA approval, and persons submitting an ANDA or 505(b)(2) application containing a patent certification of invalidity or noninfringement of a patent.

We estimate the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Hours
314.50(a) through (f), (h), and (k) (citing 21 CFR 314.53) FDA Forms 3542 and 3542a	107	2.8	296	1,684	498,464
314.50(i)(1)(i) and 314.94(a)(12)	74	1.5	111	4	444
314.52(a)(3) and 314.95(a)(3)	74	1.01	74	12	897
Total					499,805

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimates are based on the following assumptions. For the years 1998 to 2002, the annual number of original applications we have received containing a paragraph IV certification has been 61, 58, 79, 90, and 82, respectively. The annual average is 74 ((61 certifications + 58 certifications + 79 certifications + 90 certifications + 82 certifications) / 5 years = 74 certifications / year). Because the final rule requires notice of a paragraph IV certification filed in the original ANDA

or 505(b)(2) application or when the application is amended to include a paragraph IV certification or when such notice did not provide a full opportunity for a 30-month stay, this would mean that these applicants would provide one notice to NDA holders and patent owners, and, in rare instances, a second notice. We increase the frequency of response to account for these rare second notices. There may still be multiple certifications made by ANDA or 505(b)(2) applicants which

will not require notice. In previous estimates, we have combined the information collection burden for both the notice and certification. For purposes of the final rule, we assume that the certification information collection burden is 4 hours and the information collection burden for the notice is 12 hours. We also account for the multiple number of certifications that may have to be provided by an ANDA or 505(b)(2) applicant. Under pre-existing regulations, we have had