of all blood donations collected in the country.

As part of the TTIMS project, a comprehensive hemovigilance database will be created that integrates the risk factor information collected through interviews of blood donors with the resulting data from disease marker testing and blood components collected by participating organizations into a research database. Following successful initiation of the risk factor interviews, the TTIMS network is poised to be expanded to include additional blood centers and/or refocused on other safety threats as warranted. In this way, the TTIMS program will maintain standardized, statistically, and scientifically robust processes for applying hemovigilance information across blood collection organizations.

The specific objectives are to:

- Determine current behavioral risk factors associated with all HIV infections, incident HBV, and incident HCV infections in blood donors (including parenteral and sexual risks) across the participating blood collection organizations using a case-control study design.
- Determine infectious disease marker prevalence and incidence for HIV, HBV, and HCV overall and by demographic characteristics of donors in the majority of blood donations collected in the country. This will be accomplished by forming epidemiological databases consisting of harmonized operational data from ARC, BSI, NYBC, and OneBlood.
- Analyze integrated risk factor and infectious marker testing data concurrently because when taken together these may suggest that blood centers are not achieving the same degree of success in educational efforts to prevent donation by donors with risk behaviors across all demographic groups.

The respondents will be persons who donated blood in the United States and these participants will be defined as cases and controls. The estimated number of respondents is based on an overall expected participation in the risk factor survey. We estimate a case-to-control ratio of 1:2 (200 to 400) with a 50 percent case enrollment.

In the **Federal Register** of January 8, 2020 (85 FR 922), we published a 60-day notice requesting public comment on the proposed collection of information. We received two comments that were generally supportive of the collection. One comment also contained a specific suggestion that, in analyzing the data after it is collected, we utilize an ''underreporting correction factor'' identified by the commenter. The comment did not suggest that we make any changes to the Donor Risk Assessment Questionnaire or the information collection requirements. We appreciate the commenter's interest in the accuracy of the TTIMS and will consider the ''underreporting correction factor'' identified by the commenter when analyzing the data.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Questionnaire/survey	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cases and controls [2]	600	1	600	0.5 (30 minutes)	300

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Cases consist of virus-positive donations and controls represent uninfected donors.

We have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden. Based on experience with this survey, we decreased the average burden per response from 45 to 30 minutes, resulting in a change from 450 to 300 total hours.

Dated: July 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15009 Filed 7–10–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1253 (formerly FDA–1987–N–0054)]

Pentaerythritol Tetranitrate; Final Decision on Proposal To Withdraw Approval From New Drug Applications and Abbreviated New Drug Applications; Availability of Final Decision

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the initial decision of the Administrative Law Judge (ALJ), to withdraw approval of new drug applications (NDAs) and abbreviated new drug applications (ANDAs) for pentaerythritol tetranitrate (PETN), is the final decision of the Commissioner of Food and Drugs (the Commissioner) by operation of law. In the initial decision, the ALJ found that PETN had not been shown to be supported by substantial evidence consisting of adequate and well-controlled studies to be effective for prophylactic treatment of angina pectoris and ordered the withdrawal of approval for all NDAs and ANDAs. Several parties to the hearing filed exceptions to the ALJ's initial decision; however, all parties who submitted exceptions have since voluntarily withdrawn them, or FDA has deemed them withdrawn after their associated NDA or ANDA was withdrawn. Consequently, the proceeding is in the same procedural position as if no exceptions to the ALJ's initial decision had been filed. Therefore, the ALJ's initial decision has become the final decision of the Commissioner by operation of law.

Applicable Date: This notice is applicable July 13, 2020.

ADDRESSES: For access to the docket, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday

through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Rachael Vieder Linowes, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 240–402–5931.

SUPPLEMENTARY INFORMATION:

I. Background

In 1962, the Federal Food, Drug, and Cosmetic Act (FD&C Act) was amended by the Drug Amendments of 1962 (Pub. L. 87–781), and these amendments provided that new drugs could no longer be approved unless both safety and efficacy had been established for them. As amended, the FD&C Act also required FDA to evaluate drugs approved as safe between 1938 and 1962 to determine whether such drugs were effective and to withdraw approval for any applications where there was not substantial evidence of the drug's effectiveness. The person contesting the withdrawal of the approval had the burden of coming forward with evidence of effectiveness for the drug. FDA's review of these pre-1962 drugs is known as the Drug Efficacy Study Implementation program.

In a notice published in the **Federal Register** of February 25, 1972 (37 FR 4001) available at *https://www.govinfo.gov/content/pkg/FR-1972-02-25/pdf/FR-1972-02-25.pdf*), after evaluating reports received from the National Academy of Sciences/National Research Council, Drug Efficacy Study Group, and other available evidence, FDA classified certain coronary vasodilators containing PETN as ''possibly effective'' for the management, prophylaxis, or treatment of angina attacks. Parke-Davis, a Division of Warner Lambert Co. (Parke-Davis) submitted data intended to support the effectiveness of single-entity coronary vasodilator drugs containing PETN in the treatment of angina pectoris.

In a notice published in the **Federal Register** of October 15, 1984 (49 FR 40213, available at *https://www.govinfo.gov/content/pkg/FR-1984-10-15/pdf/FR-1984-10-15.pdf*), the Center for Drugs and Biologics (the Center) concluded that, after reviewing all the data previously submitted to support the effectiveness of single-entity coronary vasodilator drugs containing PETN in the treatment of angina pectoris, the data did not constitute substantial evidence of effectiveness for the listed drug products in the treatment of angina pectoris. Further, the Center issued a notice of opportunity for hearing on a proposal to withdraw approval of 15 total NDAs and ANDAs for certain coronary vasodilators containing PETN.

Multiple manufacturers responded to the notice for opportunity of hearing and submitted requests for hearings. By a notice published in the **Federal Register** of August 26, 1987 (52 FR 32170), available at *https://www.govinfo.gov/content/pkg/FR-1987-08-26/pdf/FR-1987-08-26.pdf*), the Office of the Commissioner granted requests for hearing with respect to seven NDAs and two ANDAs. Following the submission of written testimony and documentary evidence, an ALJ, Daniel J. Davidson, conducted a hearing from October 5–26, 1988. He issued his initial decision on May 10, 1989. The ALJ found that the effectiveness of PETN had not been shown to be supported by substantial evidence and, as a result, ordered that the approval of all affected NDAs and ANDAs be withdrawn.

On July 10, 1989, three parties, Parke-Davis, Jones Medical Industries, Inc. (Jones Medical) (formerly Marion Laboratories, Inc.), and Bolar Pharmaceutical Co., Inc., appealed the ALJ's initial decision by filing exceptions with the Commissioner under 21 CFR 12.125. However, since the three parties submitted their exceptions, FDA has withdrawn approval of all applications held by the three parties, either through withdrawal requests or, after notice and opportunity for hearing, for failure to file annual reports.

The Commissioner now finds that all exceptions have either been withdrawn upon the party's request or are deemed withdrawn. For these reasons, the Commissioner concludes that there are no pending appeals of the ALJ's initial decision. Parke-Davis, by a letter dated June 11, 1996, requested withdrawal of its exceptions. Watson Laboratories (successor to Bolar Pharmaceutical Co.) also submitted a letter dated November 9, 1999, requesting the withdrawal of its exceptions as to its NDA. The letter did not reference its ANDA, but the ANDA was withdrawn under a plea agreement with the United States pursuant to which Bolar Pharmaceutical Co. pled guilty to fraud and admitted to falsifying drug testing records (see July 6, 2016, 56 FR 43928), available at *https://www.govinfo.gov/content/pkg/FR-1991-09-05/pdf/FR-1991-09-05.pdf*). In light of those circumstances, the Commissioner interprets Watson Laboratories' request to withdraw exceptions to apply to both the NDA and the ANDA. When the Center for Drug Evaluation and Research (CDER) withdrew approval of Jones Medical's NDAs, CDER notified Jones Medical that its appeal in this proceeding was also regarded as withdrawn (see 62 FR 61338, available at *https://www.govinfo.gov/content/pkg/FR-1997-11-17/pdf/97-30148.pdf#page=1*). Given that Jones Medical has never filed an objection to CDER's determination that its appeal and exceptions are regarded as withdrawn, the Commissioner affirms that Jones Medical's appeal and exceptions are deemed withdrawn.

II. Conclusion and Order

Given that the exceptions have all been withdrawn or deemed withdrawn, this proceeding is now in the same procedural posture as if no exceptions had ever been filed. When parties do not file exceptions to the ALJ's initial decision, and the Commissioner does not file a notice of review, the ALJ's initial decision becomes the final decision of the Commissioner (see 21 CFR 12.120(e)). FDA will publish a notice in the **Federal Register** when an initial decision becomes the final decision of the Commissioner without appeal to or review by the Commissioner (see 21 CFR 12.120(f)).

Therefore, the ALJ's initial decision is the final decision of the Commissioner. Pursuant to the findings in the ALJ's initial decision, under section 505(e) of the FD&C Act (21 U.S.C. 355(e)) and under the authority delegated by the Secretary of Health and Human Services, there is a lack of substantial evidence that PETN will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling for prophylactic treatment of angina pectoris. Distribution of products subject to the initial decision in interstate commerce without an approved application is prohibited and subject to regulatory action (see, *e.g.,* sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

The full text of the ALJ's initial decision may be seen in the Dockets Management Staff and in this docket (see **ADDRESSES**).

Dated: July 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15010 Filed 7–10–20; 8:45 am]

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