FEDERAL RAILROAD ADMINISTRATION
Post-Accident Toxicological Testing for Non-Controlled Substances (49 CFR 219)
SUPPORTING JUSTIFICATION
OMB No. 2130-0598

Summary of Submission

- This submission is a request for an extension with change to the previous approval granted by OMB on **June 16, 2016**, which expires on **June 30, 2019**.
- FRA published the required 60-day **Federal Register** Notice on **February 22, 2019**. See 84 FR 5807. FRA received no comments in response to this notice.
- The total number of burden **hours requested** for this submission is **three (3) hours.**
- The total number of burden **hours previously approved** was **five (5) hours.**
- Total number of **responses requested** is **18.**
- Total number of **previously approved** was **32.**
- Total burden decreased by **two (2) hours** and by **14 responses**.
- **Adjustments** decreased the burden by **two (2) hours** and by **14 responses**.
- There are no **program changes** at this time.

The answer to question **number 12 itemizes the hourly burden associated with each requirement of this rule (See pp. 9-10).

1. **Circumstances that make collection of the information necessary.**

Background

Since 1985, as part of its accident investigation program, FRA has conducted post-accident alcohol and drug tests on railroad employees who have been involved in serious train accidents (50 FR 31508, August 2, 1985). If an accident meets FRA's criteria for post-accident testing (see 49 CFR 219.201), FRA conducts tests for alcohol and for certain drugs classified as controlled substances under the Controlled Substances Act (CSA), Title II of the Comprehensive Drug Abuse Prevention Substances Act of 1970 (CSA, 21 U.S.C. 801 et seq.). Controlled substances are drugs or chemicals that are

prohibited or strictly regulated because of their potential for abuse or addiction. The Drug Enforcement Agency (DEA), which is primarily responsible for enforcing the CSA, oversees the classification of controlled substances into five schedules. Schedule I contains illicit drugs, such as marijuana and heroin, which have no legitimate medical use under Federal law. Currently, FRA routinely conducts post-accident tests for the following drugs: marijuana, cocaine, phencyclidine (PCP), and certain opiates, amphetamines, barbiturates, and benzodiazepines. Controlled substances are drugs or chemicals that are prohibited or strictly regulated because of their potential for abuse or addiction. Formerly a non-controlled substance, tramadol (a synthetic opioid) was recently added to the list of controlled substances. FRA has been testing for this drug as well before it was reclassified.

FRA research indicates that prescription and OTC drug use has become prevalent among railroad employees. For this reason, FRA is adding certain non-controlled substances to its routine post-accident testing program, which currently routinely tests only for alcohol and controlled substances. FRA has added sedating antihistamines. Publication of this rule, however, in no way limits FRA's post-accident testing to the identified substances or in any way restricts FRA's ability to make routine amendments to its standard post-accident testing panel without prior notice. Furthermore, in addition to its standard post-accident testing panel, FRA always has the ability to test for "other impairing substances specified by FRA as necessary to the particular accident investigation." See 49 CFR 219.211(a). This flexibility is essential, since it allows FRA to conduct post-accident tests for any substance (e.g., carbon monoxide) that its preliminary investigation shows may have played a role in an accident.

FRA is adding tests for certain non-controlled substances to respond to the significant rise in prescription and OTC drug use in the more than 25 years since FRA began post-accident testing. In 2006, an ongoing telephone survey about the use of medications by U.S. adults found that 82 percent took at least one prescription or OTC drug, dietary supplement, or herbal remedy, each week. See **SLONE EPIDEMIOLOGY CENTER AT BOSTON UNIVERSITY, PATTERNS OF MEDICATIONS USE IN THE UNITED STATES** (2006). Also in 2006, a study commissioned by the National Community Pharmacists Association (NCPA) found that up to 75 percent of Americans reported not always taking their prescription medication as directed, 49 percent reported forgetting to take a prescribed medication, 31 percent reported not filling a prescription, 29 percent reported stopping use of a medication before its supply ran out, and 24 percent reported taking less than the recommended dosage. See **NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, TAKE AS DIRECTED: A PRESCRIPTION NOT FOLLOWED** (2006). Today, the Physician's Desk Reference contains over 13,000 prescription drugs, most of which are non-controlled substances.

In 1998, FRA first expressed concerns that § 219.103, which addresses the use of Schedule II-V controlled substances by safety-sensitive employees, may be too narrow to

cover the use of prescription and OTC drugs since most of these drugs are not controlled substances. To supplement § 219.103, FRA issued Safety Advisory 98-3 (Advisory), Recommended practices for the safe use of prescription and over-the-counter drugs by safety-sensitive railroad employees, which made recommendations to railroads on how to handle prescription and OTC drug use by their safety-sensitive employees. See 63 FR 71334, December 24, 1998).

After issuing this Advisory, FRA initiated two projects to research whether the prevalence of prescription drugs should be more closely evaluated and monitored as a possible safety concern in the rail industry. As detailed below, both projects found that prescription and OTC drug use was prevalent among railroad employees involved in reportable accidents.

In the first project, which lasted from April 2002 to April 2009, FRA asked railroad employees who had been involved in human-factor accidents that were reportable under FRA's accident reporting regulations at 49 CFR Part 225 to complete FRA surveys on their recent prescription and OTC drug use. Of the 294 human-factor accidents surveyed, only 20 percent had no employee self-reports of drug use (this 20 percent also included accidents where employees would not complete questionnaires or could not be located). In the 80 percent of surveyed accidents where prescription or OTC drug use, or both, had been self-reported, employees listed a wide variety of generic and brand name drugs, with many employees listing multiple prescription and OTC drugs, as well as dietary supplements and herbal preparations.

In 2005, FRA began a second research project that partially responded to one in a series of recommendations to FRA made by the National Transportation Safety Board (NTSB) concerning the use of prescription and OTC drugs by safety-sensitive employees. (The NTSB made similar recommendations to DOT and other DOT agencies.)

R-00-004: Establish in coordination with the U.S. Department of Transportation, the Federal Motor Carrier Safety Administration, the Federal Transit Administration, and the U.S. Coast Guard, comprehensive toxicological testing requirements for an appropriate sample of fatal highway, railroad, transit, and marine accidents to ensure the identification of the role played by common prescription and over-the-counter medications. Review and analyze the results of such testing at intervals not to exceed 5 years.

In this project, FRA re-tested a sample of 150 frozen post-accident testing urine specimens that had previously been reported as negative for the substances in the agency's standard post-accident drug testing panel. After redacting any identifying employee information, FRA used a commercially available medical professional drug testing panel to re-test these specimens for commonly used prescription and OTC drugs with known risks of adverse side effects, such as pain relievers, anti-depressants, and sedating antihistamines. Of the 150 re-tested samples, 14 (9.3 percent) tested positive for

at least one potentially impairing prescription or OTC drug. These post-accident retesting results confirmed those of FRA's human-factor accident survey, by also showing that prescription and OTC drug use was prevalent among railroad employees.

Because FRA's post-accident testing program predates both DOT's testing procedures (49 CFR part 40) and the Omnibus Transportation Employee Testing Act of 1991, neither Part 40 nor Department of Health and Human Services (HHS) guidelines apply to post-accident testing procedures and protocols. See 49 CFR 40.1. All post-accident tests are conducted on behalf of FRA by a single laboratory (FRA is revising appendix B to 49 CFR Part 219 to designate Quest Diagnostics in Tucker, Georgia, as its post-accident testing laboratory) in accordance with FRA specifications. FRA conducts compliance and quality audits of the laboratory each quarter.

As explained above, FRA intends to add testing for sedating antihistamines (a non-controlled substance) to its standard post-accident testing program to address the widespread use of prescription and OTC drugs by railroad employees. Both tramadol (again now a controlled substance) and the drugs in the sedating antihistamine category have potential side effects that could impair an employee's cognitive abilities (such as the ability to stay awake and alert or the ability to recognize and take appropriate emergency action) or cause impairing conditions (such as dizziness, agitation, and loss of coordination). These drugs are discussed below:

***** Tramadol. Tramadol is a semi-synthetic opioid. Opioids can be natural (e.g., codeine and morphine), semi-synthetic (e.g., oxycodone and hydromorphone), or wholly synthetic in origin (e.g., methadone). All opioids, regardless of origin, pose risks of sedation, and can cause abuse and dependence with prolonged use.

*****Sedating antihistamines. This widely used category of drugs includes, but is not limited to, diphenhydramine, chlorpheniramine, brompheniramine, and doxylamine. Sedating antihistamines are used primarily to treat allergy and cold symptoms, but may also be used as sleep aids or as treatment for allergic reactions such as itching and swelling. As their name implies, sedating antihistamines (as opposed to non-sedating antihistamines such as loratadine) have a known tendency to cause drowsiness. Because of this tendency, the manufacturer's instructions on the packaging and labeling of sedating antihistamines caution against use while driving, operating machinery, or performing tasks where alertness is required. Although these drugs are available at both prescription and OTC dosages, sedating antihistamines are usually taken as OTC drugs.

2. How, by whom, and for what purpose the information is to be used.

Under section 219.211 of the rule, FRA is making a routine adjustment to the controlled substances tested after serious train accidents by adding the following synthetic narcotics: Hydrocodone (Vicodin, Lorcet, others), Oxycodone (Oxycontin, Percocet, Percodan, others), Hydromorphone (Dilaudid, others), Oxymorphone (Numorphane,others), Fetanyl (Sublimaze, Actiq, others), Methadone (Dolophine, others), and Propoxyphene (Darvon, Darvocet, others). MROs will use the information reported to them to determine whether employees involved in train accidents/incidents are abusing any of these additional controlled drugs and whether changes need to be made in the railroads' drug/alcohol program to prevent such abuse and thereby reduce the numbers and severity of train accidents/incidents caused by such use/abuse. [*Note: The addition of the controlled substances listed above is not specifically mentioned in this final rule or its accompanying regulatory impact analysis because FRA has routinely made adjustment in the controlled substances on its post-accident testing panel without notice and comment. Since the inception of testing for controlled substances after serious accidents/incidents, FRA has customarily made adjustments to controlled substances on its post-accident testing based on FRA data and societal trends. FRA is publishing this rule to provide notice of the addition of non-controlled substances to FRA's post-accident testing panel.]*

In this rule, FRA is adding certain non-controlled substances –sedating antihistamines – to its standard post-accident testing program. FRA has become increasingly concerned about fitness-for-duty issues and safety issues associated with the increasing use of prescription and over-the-counter (OTC) drugs by railroad workers performing covered service. This concern is shared by the National Transportation Safety Board (NTSB). FRA will use the additional information collected for research and accident investigation purposes. The addition of non-controlled substances to the post-accident testing panel serves to inform FRA about a broader range of potentially impairing prescription and OTC drugs that may be currently contributing to the cause or severity of train accidents/incidents. Research generated by these data will inform future agency policy decisions regarding these non-controlled substances.

FRA believes that it would not be fulfilling its safety and accident investigation responsibilities if it did not research the impact of legal drugs on the occurrence or severity of significant rail accidents/incidents, including the potential risks of using drugs with known adverse effects and the potential risks of using multiple prescription and OTC drugs which may cause unintended drug interactions.

3. <u>How, by whom, and for what purpose the information is to be used</u>.

Over the years, FRA has strongly supported and highly encouraged the use of advanced automated technology, particularly electronic recordkeeping, to reduce burden on railroads and other entities that submit or retain information required by the agency. However, with the exception of the MIS reports, the types of information collected -- either for reporting or recordkeeping purposes – are not conducive to electronic collection

techniques. Nevertheless, FRA has no objection if test results for controlled substances are transmitted from the laboratories to a railroad's Medical Review Officer (MRO) by various electronic means (e.g., teleprinters, facsimile, or computer).

It should be noted that the burden for this collection of information is minuscule (a total of three (3) hours).

4. Efforts to identify duplication.

The source of the information collection requirements is unique for each separate occurrence and, therefore, there is no known duplication of this material.

Data collected are not available from any other source.

5. Efforts to minimize the burden on small businesses.

The regulation only applies to railroads and, accordingly, has no direct impact on small units of governments, business, or other organizations. FRA has not found any direct costs associated with this rule for the regulated industry. Any associated costs for conducting post-accident testing for non-controlled substances would be nominal and assumed by FRA in their entirety. Railroads would not be required to change their collection process, and would have to follow the same collection, shipping, and handling processes they currently follow. This means that individuals subject to post-accident testing would provide the same specimens currently required, which would then be tested for tramadol and sedating antihistamines at FRA's expense. Since FRA would use these results for research and accident investigation purposes only, tramadol and sedating antihistamines test results would not be reported directly to either the employee or the employing railroad. This non-reporting process would apply to both surviving and fatally injured employees. Thus, no hourly burden is associated with the testing for non-controlled substances. Moreover, no monetary costs would be imposed on the industry as a result of this addition. As a result, FRA certifies that this rule will not have a significant economic impact on a substantial number of small entities.

6. Impact of less frequent collection of information.

If this collection of information were not conducted, or conducted less frequently, rail safety in the U.S. might be seriously jeopardized. Specifically, without the results of post-accident toxicological tests being reported to Medical Review Officers (MROs), railroads would have no way to determine whether specific controlled substances were being abused by their employees and causing serious train accidents/incidents. In particular, without testing for the additional controlled substances (synthetic narcotics -- hydrocodone, oxycodone, hydormorphone, oxymorphone, fentanyl, methadone, propoxyphene, tramadol) that are being included as a routine part of FRA's standard

testing panel under section 219.211, railroads would have no idea that these other controlled substances are being used/abused by their employees. Further, without this information being reported to MROs, railroads would be unable to assess/determine whether their alcohol and drug misuse prevention programs are effective and whether these additional controlled substances need to be added to their misuse programs. If railroads did not have effective alcohol and drug misuse prevention programs and if these programs were not carefully monitored, railroad employees working in safety-sensitive positions might abuse/continue to abuse alcohol and drugs while on-duty, or just prior to coming on-duty. This could lead to greater numbers of – and perhaps more severe – accident/incidents where train crews, other railroad employees, passengers, and innocent bystanders are injured or killed. Particularly in the case of a catastrophic accident or an accident involving the release of radioactive or other hazardous materials, the number of casualties and harm to the environment and surrounding communities might be great.

To be effective, a safety program requires timely information. Collection of this information less frequently would render the information obsolete and meaningless, and would impair FRA's and railroads safety programs. If future experience indicates a lesser frequency is warranted, the agency would carefully review this part of its regulatory safety program and make necessary revisions accordingly.

Without the collection of information related to testing of non-controlled substances, specifically sedating antihistamines, FRA would not be able obtain and analyze data on the extent to which prescription and over-the-counter (OTC) drug use by railroad employees potentially affects rail safety. Studies have shown a steady increase in the daily use of prescription drugs, OTC drugs, vitamins, and herbal and dietary supplements by both railroad workers and the general population. Although most prescription drugs and all OTC drugs are non-controlled substances, many commonly used ones, such as antihistamines and muscle relaxants, carry label warnings against driving or moving heavy machinery because of their potential sedating effects. Moreover, even prescription and OTC drugs that do not carry such warnings can have unintended side effects when taken in combination with other drugs, when not used in accordance with directions, or when a user has an unusual reaction. Thus, it is critically important that FRA collects such direct testing data to determine whether use of prescription and OTC drugs is a factor in the cause or severity of rail accidents/incidents because of their possible impairing side effects. With such concrete data, FRA can inform agency policy and determine whether any agency action is needed to further enhance rail safety and reduce the number and severity of rail accidents/incidents that occur each year throughout the country.

In sum, this collection of information assists FRA and railroads in promoting and maintaining a safe rail environment. As such, it furthers FRA’s main mission.

7. <u>Special circumstances</u>.

All reporting and recordkeeping requirements are within these guidelines.

8. Compliance with 5 CFR 1320.8.

As required by the Paperwork Reduction Act of 1995 and 5 CFR 1320, FRA published a notice in the Federal Register on **February 22, 2019**, soliciting comment on these information collection requirements from the public, railroads, and other interested parties. See 84 FR 5807.

FRA received no comments in response to this notice.

9. Payments or gifts to respondents.

There are no monetary payments or gifts made to respondents associated with the information collection requirements contained in this regulation.

10. Assurance of confidentiality.

Regarding routing testing for controlled substances, no assurances of confidentiality have been provided to affected respondents. FRA maintains a set of accident investigation files. FRA will not maintain a system of records that will permit the identification of records by an individual name. FRA does hold in confidence information concerning medically authorized use of controlled substances, pursuant to 5 U.S.C. 552 (b)(6), except where the information is deemed material to determination of accident causation. The random testing programs for alcohol and drugs require that results of random tests and related medical information be held in confidence, except as necessary to effect discipline and/or referral for rehabilitation.

Regarding testing for non-controlled substances, FRA asked in the NPRM for comment on whether post-accident testing results for sedating antihistamines – because they are primarily over-the-counter (OTC0 drugs – should be handled differently than test results for controlled substances and prescription drugs. After a review of the comments, FRA has decided to keep the post-accident test results for these non-controlled substances (tramadol and sedating antihistamines) confidential while it continues to obtain and analyze data on the extent to which prescription and over-the-counter (OTC) drug use by railroad employees potentially affects rail safety.

11. Justification for any questions of a sensitive nature.

These requirements have nothing to do with sensitive matters such as sexual behavior and attitudes, religious beliefs, and other matters commonly considered private.

12. Estimate of burden hours for information collected.

Note: Although there are currently 741 railroads currently operating, the number of railroads affected by this rulemaking is 692.

Per OMB's request, FRA is including the dollar equivalent cost to the requested burden hours in this renewal information collection submission. Based on the 2017 AAR publication, Railroad Facts, for executives/officials/staff assistants, FRA estimates the average hourly wage rate for railroad Medical Review Officers (MROs) at $110 per hour. This estimate includes 75 percent overhead costs.

SUBPART C – POST-ACCIDENT TOXICOLOGICAL TESTING

Analysis and follow-up - MRO [219.211(a), (b), & (c)]

(a) The laboratory designated in appendix B to this Part undertakes prompt analysis of specimens provided under this subpart, consistent with the need to develop all relevant information and produce a complete report. Specimens are analyzed for alcohol, controlled substances, and non-controlled substances specified by FRA under protocols specified by FRA. These substances may be tested for in any form, whether naturally or synthetically derived. Specimens may be analyzed for other impairing substances specified by FRA as necessary to the particular accident investigation. [*Note: The burden for alcohol and drug testing of railroad employees is included under DOT's Part 40 information collection submission. Consequently, there is no additional burden associated with this requirement*.]

(b) Results of post-accident toxicological testing for controlled substances conducted under this subpart are reported to the railroad's Medical Review Officer and the employee. * * *

Results of post-accident toxicological testing under this subpart are reported to the railroad's Medical Review Officer (MRO) and the employee. The MRO and the railroad must treat the test results and any information concerning medical use or administration of drugs provided under this subpart in the same confidential manner as if subject to subpart H of this part, except where publicly disclosed by FRA or the National Transportation Safety Board.

(c) With respect to a surviving employee, a test reported as positive for alcohol or a controlled substance by the designated laboratory must be reviewed by the railroad's Medical Review Officer with respect to any claim of use or administration of medications (consistent with § 219.103) that could account for the laboratory findings. The Medical Review Officer must promptly report the results of each review to the Associate Administrator for Safety, FRA, Washington, DC, 20590. Such report must be in writing and must reference the employing railroad, accident/incident date, and location, and the envelope must be marked "**ADMINISTRATIVELY CONFIDENTIAL: ATTENTION**

ALCOHOL/DRUG PROGRAM MANAGER." The report must state whether the MRO reported the test result to the employing railroad as positive or negative and the basis of any determination that analytes detected by the laboratory derived from authorized use (including a statement of the compound prescribed, dosage/frequency, and any restrictions imposed by the authorized medical practitioner). Unless specifically requested by FRA in writing, the Medical Review Officer must not disclose to FRA the underlying physical condition for which any medication was authorized or administered.

As a result of the final rule, FRA will be testing additional controlled substances. Consequently, FRA estimates that the number of MRO reports will increase. Approximately 16 reports will be prepared annually by MROs and 16 copies of the report will be sent to railroad employees. It is estimated that it will take approximately 15 minutes to prepare the report and forward it to FRA and another five minutes to make a copy of the report and send it to the railroad employee. Total annual burden for this requirement is three (3) hours.

Respondent Universe: 692 railroads

Burden time per response: 15 minutes + 5 minutes

Frequency of Response: On occasion

Annual number of Responses: 9 reports + 9 report copies
Annual Burden: 3 hours
Annual Cost: $330 ($110 p/hr. x 3 hrs.)

Calculation: 9 reports x 15 min. + 9 report copies x 5 min. = 3 hours

Total annual burden for this entire requirement is three (3) hours, and total dollar equivalent cost for these burden hours is $330.

Total annual burden for this entire information collection is **three (3) hours,** and total dollar equivalent cost for these burden hours is **$330**.

13. Estimate of total annual costs to respondents.

Respondent Costs

There are no other costs to respondents other than the hourly burden reflected in the response to question 12 above. [*Note: The costs for the Custody and Control Forms (CCFs) are the responsibility of the Department of Health and Human Services (DHHS*), *and the costs for post-accident toxicological testing for non-controlled substances resulting from this rulemaking will be borne by FRA*.]

14. Estimate of Cost to Federal Government.

There is an additional cost to FRA resulting from the additional controlled substances (synthetic opioids) included in the standard testing panel of railroad employees that will undergo laboratory testing post-accident.

FRA estimates the annual cost for the additional controlled substances post-accident toxicological testing of railroad employees as follows:

$112 per test 196 tests per year

$ 21,952 TOTAL

15. Explanation of program changes and adjustments.

This is a request for an extension with change of the last approved submission. FRA is requesting a total burden of **three (3) hours,** and **18 responses**.

TABLE FOR ADJUSTMENTS

Part 219 Sec./ Form Number	Responses & Avg. Time (Previous Submission)	Responses & Avg. Time (This Submission)	Burden Hours (Previous Submission)	Burden Hours (This Submission)	Difference (plus/minus)
219.211(c) – Medical Review Officer report to FRA of a positive test for alcohol or controlled substance by surviving employee(s) after	16 reports + 16 report copies 15 minutes + 5 minutes	9 reports + 9 report copies 15 minutes + 5 minutes	5 hours	3 hours	- 2 hours - 14 responses

accident/incident and copy of report to employing railroad					

Adjustments above decreased the burden by **two (2) hours** and by **14 responses**.

There are no **program changes** at this time.

The current OMB inventory for this information collection shows a total burden of *five (5) hours* and *32 responses*, while the present submission exhibits a total burden of *three (3) hours* and *18 responses*. Hence, there is a burden decrease of **two (2) hours** and **14 responses**.

There are no additional costs to respondents other than the burden hours specified in the answer to question number 12 of this document. So, there is **no** change in cost to respondents.

16. Publication of results of data collection.

The information concerning impairment in an accident setting, which is received pursuant to this program, will be published in a subset of data contained in FRA's annual Accident/Incident Bulletin. All of the remaining information obtained under this program is intended for use by the Office of Safety technical staff in its ongoing accident prevention activities or will be used by railroads in monitoring compliance by their employees with the prohibitions on alcohol and drug use.

17. Approval for not displaying the expiration date for OMB approval.

Once OMB approval is received, FRA will publish the approval number for these information collection requirements in the Federal Register.

18. Exception to certification statement.

No exceptions are taken at this time.

Meeting Department of Transportation (DOT) Strategic Goals

This information collection supports the top DOT strategic goal, namely transportation safety. Without this collection of information, rail safety in the U.S. would be seriously jeopardized. Specifically, without the results of post-accident toxicological tests being reported to Medical Review Officers (MROs), railroads would have no way to determine whether specific controlled substances were being abused by their employees and causing serious train accidents/incidents. In particular, without testing for the additional controlled substances (synthetic narcotics -- hydrocodone, oxycodone, hydormorphone, oxymorphone, fentanyl, methadone, propoxyphene, tramadol) that are being added as a routine part of FRA's standard testing panel under section 219.211, railroads would have no idea whether these other controlled substances are being used/abused by their employees. Further, without this information being reported to MROs, railroads would be unable to assess/determine whether their alcohol and drug misuse prevention programs are effective and whether these additional controlled substances need to be added to their misuse programs. If railroads did not have effective alcohol and drug misuse prevention programs and if these programs were not carefully monitored, railroad employees working in safety-sensitive positions might abuse/continue to abuse alcohol and drugs while on-duty, or just prior to coming on-duty. This could lead to greater numbers of – and perhaps more severe – accident/incidents where train crews, other railroad employees, passengers, and innocent bystanders are injured or killed. Particularly in the case of a catastrophic accident or an accident involving the release of radioactive or other hazardous materials, the number of casualties and harm to the environment and surrounding communities might be great.

Without the collection of information related to testing of non-controlled substances, specifically tramadol and sedating antihistamines, FRA would not be able obtain and analyze data on the extent to which prescription and over-the-counter (OTC) drug use by railroad employees potentially affects rail safety. Studies have shown a steady increase in the daily use of prescription drugs, OTC drugs, vitamins, and herbal and dietary

supplements by both railroad workers and the general population. Although most prescription drugs and all OTC drugs are non-controlled substances, many commonly used ones, such as antihistamines and muscle relaxants, carry label warnings against driving or moving heavy machinery because of their potential sedating effects. Moreover, even prescription and OTC drugs that do not carry such warnings can have unintended side effects when taken in combination with other drugs, when not used in accordance with directions, or when a user has an unusual reaction. Thus, it is critically important that FRA collects such direct testing data to determine whether use of prescription and OTC drugs is a factor in the cause or severity of rail accidents/incidents because of their possible impairing side effects. With such concrete data, FRA can inform agency policy and determine whether any agency action is needed to further enhance rail safety and reduce the number and severity of rail accidents/incidents that occur each year throughout the country.
In sum, this collection of information assists FRA and railroads in promoting and maintaining a safe rail environment. As such, it furthers FRA's main mission.

In this information collection, as in all its information collection activities, FRA seeks to do its utmost to fulfill DOT Strategic Goals and to be an integral part of One DOT.