Issued in Kansas City, Missouri, on July 8, 1998.

Michael Gallagher,

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DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Parts 234, 241, 250, 298, and 374a

[Docket No. OST–98–4043; Notice No. 98–18]

RIN 2105–AC71

Aviation Data Requirements Review and Modernization Program

AGENCY: Office of the Secretary, DOT.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Department on its own initiative is requesting public comments from reporting carriers and aviation data users on the nature, scope, source, and means for collecting, processing, and distributing airline traffic, fare, and financial data. Specifically, the Department is inviting comments on whether existing airline traffic, fare, and financial data should be amended, supplemented, or replaced; whether selected forms and reports should be retained, modified, or eliminated; whether the Department should require all aviation data to be filed electronically; and how the aviation data system should be reengineered to enhance efficiency and to reduce costs for both the Department and the airline industry.

It is the Department's preliminary position that its current aviation data systems may not provide sufficiently reliable data in some areas to ensure that the Department can fully meet its regulatory and statutory responsibilities, and that its aviation data requirements should be reviewed and modernized.

The Department may engage one or more contractors to assist it in its aviation data requirements assessment and in the reengineering of the Department's aviation data systems.

DATES: Comments must be submitted on or before September 14, 1998. Reply comments must be submitted on or before October 13, 1998.

ADDRESSES: Comments are to be filed in Room PL–401, Docket OST–98–4043, U.S. Department of Transportation, 400 7th Street, S.W., Washington, D.C. 20590. Late filed comments will be considered to the extent practical. To facilitate consideration of comments, each respondent should file six copies of its comments.

FOR FURTHER INFORMATION CONTACT: Regis P. Milan, Office of Aviation Analysis, (202) 366–2344, or David B. Richards, Office of International Aviation, (202) 366–2432; 400 7th Street, S.W., Washington, D.C. 20590.

SUPPLEMENTARY INFORMATION:

Background

Public Law 98–443 requires the Department of Transportation, under the authority of the Secretary of Transportation (49 U.S.C. 329(b)(1)), to collect and disseminate information on civil aeronautics, other than that collected and disseminated by the National Transportation Safety Board. In meeting this responsibility, the Department collects traffic and financial data submitted under 14 CFR Part 241 (Uniform System of Accounts for Large Certificated Air Carriers) and traffic data submitted under 14 CFR Part 298 (Exemptions for Air Taxi and Commuter Air Carriers). The Department also collects certain traffic data from foreign air carriers for flights to or from the U.S. under 14 CFR Part 217 and Section 25 of 14 CFR Part 241. The Department collects service quality data from U.S. carriers submitted under 14 CFR Part 234 (Airline Service Quality Performance Reports), and under 14 CFR 250 it collects information on passengers denied boarding. In addition, under Part 374a, airlines are required to report information on any extensions of credit for air transportation services provided to federal political candidates.

The Department uses these data in a variety of ways, including monitoring the fitness of individual carriers and the economic health of the airline industry, assessing the competitiveness of aviation markets, providing consumers with data to make decisions on air travel, providing data for forecasting traffic and for airport funding and traffic control purposes, and providing the basis for policy decisions on aviation matters, including international aviation negotiations.

The Department maintains two large traffic data bases, one for domestic and international passenger origin-destination movements, including ticket price and itinerary, which are submitted by U.S. carriers only (Section 19–7 of Part 241, the Passenger Origin-Destination Survey), and another for aircraft flight data submitted by U.S. and foreign air carriers (Section 25 of Part 241 and Part 217, the T–100 and T–100(f) segment and on-flight market reports).

The Department collects Form 41 data, which consist of comprehensive financial and traffic data reported by large and small air carriers. Form 41 also includes fuel cost and consumption and aircraft fleet inventory data.

The Department requires air taxi and commuter carriers to report limited traffic and market data on Form 298C.

The Department also collects data on oversales/denied boardings, air service quality performance, and extensions of credit by airlines to federal political candidates.

The Department's aviation databases are used by a number of federal departments and agencies, Congress, state and local authorities, airlines, airports, manufacturers, industry associations, consultants, academics, researchers, financial analysts, investors, and the general public.

For the most part, the data collected by the Department are based upon regulatory requirements designed for an economic environment that has evolved significantly since enactment of the Airline Deregulation Act in 1978. Many changes in the airline industry have taken place since these data reporting systems were established. Nearly all domestic air carriers now operate hub-and-spoke systems, have extensive code-sharing and other marketing agreements with other carriers, offer frequent flyer programs, provide ticketless travel, and use integrated computer reservation systems. This environment represents a marked change from the linear, point-to-point systems in place 20 years ago, when the domestic airline industry was deregulated. Internationally, the last few years have seen the development of global, multi-national carrier alliances and an increasing number of open-skies and liberalized-entry agreements with other nations.

Along with these changes, the needs of the Department and other aviation data users have evolved and expanded, while the collected data and associated processing systems have changed slowly. However, the Department has significantly reduced the reporting burden on the industry by eliminating some Form 41 schedules and line items over the last 20 years. Nonetheless, the Department intends to reexamine whether all data items that we now collect remain relevant to today's economic and regulatory environment.

Request for Comments

We are issuing this advance notice of proposed rulemaking to invite comments on whether traffic, fare, and

financial data reporting systems should be retained, amended, supplemented, or replaced; whether other selected forms and reports which are less utilized by the Department and other government users should be retained, compressed, or deleted; and finally, whether the Department should require all data to be filed by electronic communication means (e.g., Internet, direct-wire) or on magnetic media (e.g., tape, disk, cassette).

The Department now collects data from over 400 U.S. and foreign airlines for certain data collections. These data must be processed, validated, and edited. We are seeking comments on alternative data and collection methods to address deficiencies in the structure of these data systems.

We request comments on whether there are alternate, more reliable sources of these data, and whether changes to data items may make these data more useful.

Note: We welcome comments on all aspects of our data systems. However, for identification, reference, and administrative convenience, we have specifically numbered particular requests for comments by section, with an identification number placed after each request. Please use these identifiers in your response.

A. The T–100 System—Report of Traffic, Capacity, and Statistics

This database provides airport pair traffic and capacity data by non-stop segment by aircraft type and on-flight market. Schedule T–100 reports are filed by all large certificated air carriers, where large certificated air carriers are defined as those that conduct operations using ''large'' aircraft (aircraft with more than 60 seats or 18,000 pounds of payload capacity, 14 CFR Parts 217.3 and 241.25). However, carriers conducting only domestic charter or all-cargo operations are not required to file Schedule T–100, with the exception of intra-Alaska cargo operations (Part 241, Section 19–1(a)). The T–100 system does not require U.S. and foreign carriers who exclusively operate aircraft with 60 or fewer seats to report T–100 data. Foreign air carriers serving the U.S. generally have the same reporting requirements as U.S. carriers, except that they instead file Schedule T–100(f).

The Department last year reviewed its Schedule T–100 and T–100(f) traffic data systems and determined that the data-confidentiality restrictions for international service should be shortened to no earlier than six months after the submission date for the data; reporting of available seats and payload weight should be added to the reporting requirements for foreign carriers, similar to that required for U.S. carriers; and the requirement to report passenger data by cabin configuration should be eliminated (62 FR 6715–6719, February 13, 1997).

We request that respondents provide specific comments on the following matters:

[A–1] Is there a continuing need to collect T–100/T–100(f) data? Explain the usefulness of these data in satisfying your requirements.

[A–2] Is there a way to modify or restructure T–100/T–100(f) data to make them more functional?

[A3] Are there alternate sources of and/or more efficient modes for delivery of these data to the Department?

[A–4] Should the Department require T–100/T–100(f) data from carriers who exclusively operate aircraft with fewer than 60 seats?

[A–5] Should the Department require T–100 data from domestic all-cargo carriers?

[A–6] If yes to A–4 and/or A–5, what criteria should be used in setting the data reporting threshold (e.g., aircraft size, air carrier operations, annual operating revenues, revenue passenger enplanements, number of flights, some combination of these specified criteria, or other unspecified criteria)?

[A–7] Are there alternate sources of comparable data available for smaller carriers or domestic all-cargo carriers?

[A–8] Should the Department amend T–100 and T–100(f) to require that international data include summary citizenship data (e.g., U.S. or non-U.S.)?

B. The Origin and Destination Survey of Airline Passenger Traffic

The O&D Survey (Survey) provides U.S. air carrier traffic using a ten percent sample of ticketed passengers. These data are reported for the scheduled operations only of large U.S. carriers, except where certain foreign carriers provide data similar to those required of U.S. carriers as a condition for approval of, and antitrust immunity for, carrier alliances (*See* e.g., Order 96–11–1, November 1, 1996). U.S. carriers who exclusively operate aircraft with 60 or fewer seats do not report Survey data for their operations and such data are included in the Survey only if incidentally reported as part of an itinerary reported by a large carrier.

The Survey was originally designed in the early 1960s, with fare data (from the ticket) added in 1979. As with other regulatory reporting requirements, time and technology have rendered this data collection methodology virtually obsolete. Nearly all carriers now rely on computer reservation systems for reservation/ticketing procedures, and a significant and growing percentage of passengers are traveling using ''ticketless or electronic'' procedures. Carrier use of the physical ticket for revenue accounting and control purposes is rapidly declining.

The processing of the current Survey data is costly both for the reporting carriers and the Department. Moreover, the Department's quarterly release of the domestic Survey data has been unacceptably delayed because of significant carrier submission errors and omissions. While imposing economic sanctions for filing such poor quality data may improve their accuracy and timeliness, the fundamental problem is that this O&D Survey data system is hampered by outmoded and inefficient transmission, collection, and processing procedures that rely extensively on paper tickets.

[B–1] Is there a continuing need to collect O&D data? Explain the usefulness of these data in satisfying your requirements.

[B–2] Is there a way to modify or restructure O&D data to make them more functional?

[B–3] Are there alternate sources of and/or more efficient modes for delivery of these data to the Department?

[B–4] Should the Department require O&D data from carriers who exclusively operate aircraft with fewer than 60 seats?

[B–5] If yes to B–4, what criteria should be used in setting the data reporting threshold (e.g., aircraft size, air carrier operations, annual operating revenues, revenue passenger enplanements, number of flights, some combination of these specified criteria, or other unspecified criteria)?

[B–6] Should O&D data be collected for U.S. domestic services and international services of U.S. air carriers only, as is the procedure under the current Survey, or should foreign air carrier international O&D data, involving a U.S. point in the flight itinerary, be required and processed in the Survey?

[B–7] If it is determined that foreign air carrier international O&D data should be required and processed in the Survey, should those carriers be required to submit information on the full flight itineraries or only on those flight segments to/from the U.S., or some combination thereof?

[B–8] Should there be confidentiality restrictions imposed for access to international data included in the Survey, and if so, what should be the degree and duration of such access restrictions?

[B–9] What should be the time-frame for submission to the Department—weekly, monthly, or quarterly?

Other Automated Sources of O&D Data

The Department wishes to consider whether there are alternatives to the current ticket-based O&D System, especially ones that could be based on existing internal automated data systems maintained by airlines and/or computer reservation systems (CRSs). As an example, there is a CRS-based data file called the Transaction Control Number (TCN) files. In the process of ticketing airline passengers, airlines and related computer reservation systems electronically record the majority of transactions in the standard TCN formats for various accounting, reconciliation, and seat inventory control purposes. Under a current industry data interchange program, many airlines and CRSs routinely exchange the TCN data through the Airline Tariff Publishing Company (ATPCO) electronically on a daily basis. The Department believes that these TCN data could provide an alternative, less expensive source of traffic and fare data.

We request that respondents provide specific comments on the following matters:

[B–10] List and describe alternative data sources, such as TCN, that could provide the types of comprehensive passenger O&D itinerary and fare data we are seeking, and the potential advantages and disadvantages of each source.

[B–11] If the Department decides to use TCN or alternative data as the basis of a new O&D Survey, should carriers continue to submit data independently to the Department, or should such data be submitted via a common exchange (such as a CRS or common exchange point like ATPCO)?

[B–12] Under a new system, should the replacement O&D data be submitted for ticketed or booked passengers only, or should such data be held until reconciliation, e.g. until the reservation is actually used (as evidenced by a coupon lifted at the time of flight) or is canceled?

[B–13] What are carriers' best cost estimates for the submission of domestic and international TCN data to the Department via CRS or ATPCO?

[B–14] What are carriers' best cost estimates for the submission of data from other potential sources?

[B–15] What are the best cost estimates of carriers who do not use CRS services or ATPCO for reconciliation or control purposes to file independent submissions of this type of data to the Department directly or via an intermediary?

C. Form 41, Uniform System of Accounts and Reports of Financial and Operating Statistics for Large Certificated Air Carriers

This database provides U.S. air carrier financial data, predicated on a uniform system of accounts, and selected traffic statistics, generally termed the Form 41 schedules. A list of such schedules is shown in 14 CFR Part 241, Section 22. These schedules include the balance sheet, profit and loss statement, various operating expense schedules, and summary traffic and capacity schedules.

We request that respondents provide specific comments on the following matters:

[C–1] Is there a continuing need to collect Form 41 data? Explain the usefulness of these data in satisfying your requirements.

[C–2] Is there a way to modify restructure Form 41 data to make them more functional?

[C–3] Are there alternate sources of and/or more efficient modes for delivery of these data to the Department?

D. Commuter, Part 298, Exemptions for Air Taxi and Commuter Air Carrier Operations

This rule provides air taxi and commuter air carriers certain exemptions from traffic and financial data reporting required of large certificated air carriers. However, less detailed reporting schedules (Form 298–C) are required, including, for example, the full reporting of on-line origin-destination passengers instead of the Department's standard O&D Survey, expense reporting by general category, rather than by detailed sub-account, and simplified quarterly reporting of traffic rather than the monthly T–100 schedule.

We request that respondents provide specific comments on the following matters:

[D–1] Is there a continuing need to collect Form 298–C data? Explain the usefulness of these data in satisfying your requirements.

[D–2] Is there a way to modify or restructure Form 298–C data to make them more functional?

[D–3] Are there alternate sources of and/or more efficient modes for delivery of these data to the Department?

[D–4] Should the Department retain, modify, or eliminate the 60-seat exemption under Part 298?

[D–5] Air taxi and commuter carriers are asked to indicate their use of computer reservation systems, with specific attention to the possible use of TCN data derived from CRS records to replace the Survey.

E. Part 234, Airline Service Quality Performance Reports

These data are collected from air carriers accounting for at least one percent of domestic scheduled passenger revenues. This monthly report includes flight delays, on-time flight performance, enplaned passengers, and the number of mishandled-baggage reports filed with air carriers.

We request that respondents provide specific comments on the following matters:

[E–1] Is there a continuing need to collect Part 234 data? Explain the usefulness of these data in satisfying your requirements.

[E–2] Is there a way to modify Part 234 data to make them more functional?

[E–3] Are there alternate sources of and/or more efficient modes for delivery of these data to the Department?

F. Part 250, *Oversales*, requires that U.S. and foreign air carriers report various data on the number of passengers that are denied boarding, and the total number of boardings, each quarter. Our reporting requirements were last reviewed in 1995.

We request that respondents provide specific comments on the following matters:

[F–1] Is there a continuing need to collect Part 250 data? Explain the usefulness of these data in satisfying your requirements.

[F–2] Is there a way to modify Part 250 data to make them more functional?

[F–3] Are there alternate sources of and/or more efficient modes for delivery of these data to the Department?

G. Part 374a, *Extension of Credit by Airlines to Federal Political Candidates*, requires air carriers to make monthly reports with respect to credit for transportation furnished to political candidates, or persons acting on behalf of candidates, during the period from six months before nomination or election, until the date of election. Continuing reports are to be made until a filing indicates that no debt is owed the carrier.

We request that respondents provide specific comments on the following matters:

[G–1] Is there a continuing need to collect Part 374a reports? Explain the usefulness of these data in satisfying your requirements.

[G–2] Is there a way to modify or restructure Part 374a reports to make them more functional?

[G–3] Are there alternate sources of and/or superior submission techniques for these reports?

H. Electronic Filing of Data

The Department currently accepts data submissions either in paper form or on magnetic disk or tape. Most large carriers submit the bulk of their data on magnetic media, with large data submissions, such as the Passenger Origin-Destination Survey and T–100 market reports nearly universally submitted on tape or cassette. Electronic submission of data can be processed more quickly, and at lower cost, than similar data submitted in paper form.

The Department now accepts the official filing of international fare and fare rules tariffs electronically (See 14 CFR Part 221 and 61 FR 18070–18075, April 24, 1996). Given the Department's limited resources, it would be impossible to process the volume of tariff data received if these data were filed in a wholly paper environment. Similarly, the Department is increasingly burdened by the filing of required financial and traffic data in paper form.

We request that respondents provide specific comments on the following matters:

[H–1] All air carriers who supply aviation data to the Department are requested to comment on their ability to file data electronically or on magnetic media, i.e., via tape or disk, or over the Internet.

[H–2] If certain large database material now accepted by the Department in electronic form (e.g., the T–100/T–100(f), Origin-Destination Survey, and 298–C reports) are submitted on paper, relevant carrier respondents are requested to indicate why magnetic media are not employed for their submissions.

Contact Persons

We recognize that formal comments submitted to the Department on rulemaking matters are usually submitted by corporate counsel. However, we are seeking comments regarding complex technical issues in anticipation of a formal rulemaking, in areas which are generally outside the area of expertise of legal counsel. It would aid in our evaluation of any technical comments to be able to contact persons with direct knowledge of technical issues being commented upon. Respondents are urged to supply the names, telephone numbers, and addresses of knowledgeable individuals who can be contacted for a more detailed discussion of any technical matters that the respondent counsel cannot answer directly. There may be multiple contact persons for any particular item, or in total. These contact persons should be listed on the last page of any submitted filing, along with their area(s) of expertise.

Regulatory Process Matters

Executive Orders 12612 and 12866

The Department has determined that the proposed notice of proposed rulemaking is not a significant regulatory action under Executive Order 12866. However, the proposed rule may be significant under the Department's Regulatory Policies and Procedures (44 CFR 11304), because of substantial industry interest and because it may result in a reduction in paperwork and filing burden for U.S. carriers. The Department has also analyzed the proposal in accordance with the principles and criteria contained in Executive Order 12612 (''Federalism''), and has determined that the rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. This rule would not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601 et seq., was enacted by Congress to ensure that small entities are not unnecessarily and disproportionately burdened by government regulations. The Act requires agencies to review proposed regulations that may have a significant economic impact on a substantial number of small entities. For purposes of this notice, small entities include air taxis, commuter air carriers, and smaller U.S. and foreign airlines.

Although we do not believe the existing rule imposes a significant economic impact on a substantial number of small entities, it does affect many small entities. For that reason, we specifically seek public comment on what steps we can take to lessen or eliminate any burdens it imposes on small entities.

Paperwork Reduction Act

Our current rules contain significant collection-of-information requirements. Changes we may propose will be subject to the Paperwork Reduction Act, Public Law No. 96–411, 44 U.S.C. Chapter 35. The revised rules are expected to result in a net paperwork reduction for the industry.

Regulation Identifier Number

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

Patrick V. Murphy,

Deputy Assistant Secretary for Aviation International Affairs.

Robert A. Knisely,

Acting Director, Bureau of Transportation Statistics.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 812

[Docket No. 98N–0394]

RIN 0910–ZA14

Medical Devices; Investigational Device Exemptions

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the Investigational Device Exemptions (IDE) regulation. The proposed regulatory changes are intended to reflect amendments to the Federal Food, Drug, and Cosmetic Act (the act) by the FDA Modernization Act of 1997 (FDAMA). These amendments provide that the sponsor of an IDE may modify the device and/or clinical protocol, without approval of a new application or supplemental application, if the modifications meet certain criteria and if notice is provided to FDA within 5 days of making the change. The proposed rule also defines the credible information to be used by sponsors to determine if the criteria are met.

DATES: Submit written comments on or before September 28, 1998. Written comments on the information collection provisions should be submitted by August 14, 1998.

ADDRESSES: Submit written comments on the proposed rule to the Documents Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.