controlled conditions in sufficient quantity to conduct the side-by-side testing of products. Applicants are encouraged to discuss with CBER what data are necessary to compare products, as such data may range from analytical testing to full clinical trial(s).

7. Review timeframes and submission times

There may be cases where applicants wish to submit an ELA for a pilot facility prior to submitting a companion PLA. A statement that the facility is ready for inspection at the time of submission should be included. FDA ordinarily intends to inspect at the time the facility is manufacturing the product for which licensure is sought. It is possible that, in some cases, inspection of the establishment could take place before the submission of the PLA. It is also possible for the ELA to be submitted after the PLA as discussed above.

CBER intends to review PLA's and ELA's submitted at different times under the normal timeframe targets of the managed review process (from the date of receipt at CBER, 12 months for standard and 6 months for priority applications; 6 months for supplements). CBER intends to issue the appropriate action letter (approved, approvable, or not approvable) to complete its action on any application.

Applicants should be aware that submitting the ELA and PLA at separate times will not necessarily reduce the approval time when compared to concurrent submission. Early submission of applications may, however, allow earlier feedback from CBER on deficiencies in an application that can be addressed by the applicant sooner than would otherwise be possible. In all cases described above, CBER intends to approve PLA's, ELA's, or supplements concurrently.

In cases of shared manufacturing arrangements (see 57 FR 55544 at 55545), the PLA's for the intermediate product(s) and end product should be submitted concurrently in order for a complete review of the product to occur, since determining the approvability of the end product will depend upon information in the intermediate product PLA's. The ELA's may be submitted at different times from the PLA's.

Applicants should consider carefully the consequences of the timing of any submission on the use of CBER resources. It is expected that applicants will use the flexible submission times in cases of need. Applicants should recognize that the filing of submissions which are premature or incomplete will result in unnecessary resource commitments by CBER and the applicant. It is therefore recommended that applicants do not submit an ELA before favorable preliminary data or information from clinical trials of the product is available. For products intended for use in serious and life-threatening diseases, applicants should consider submitting the ELA and PLA concurrently to prevent a situation from occurring where otherwise approvable product cannot be approved because the facility is not yet ready to be licensed.

If a scenario exists that is not covered in this guidance document, the applicant should seek guidance by contacting the appropriate applications division in the Offices of Therapeutics Research and Review, Blood Research and Review, or Vaccines Research and Review, or the Division of Establishment Licensing.

8. Availability of product at the time of licensure

If an applicant requests licensure for a pilot facility, this choice may affect the amount of product available at the time of approval. For important new products for use in treating serious and life-threatening illnesses, the ramifications of limited availability of the product at the time of approval should be assessed by the applicant.

Dated: June 26, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–17022 Filed 7–7–95; 10:53 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

National Biological Service

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). An expedited review has been requested in accordance with the Act so that approval can be received by August 18, 1995, permitting the National Biological Service to comply with Executive Order 12862 reporting requirements for 1995. Copies of the proposed collection of information and related forms may be obtained by contacting the Service's clearance officer at the phone number listed below. Comments and suggestions on the proposal should be made directly to the bureau clearance officer and the Office of Management and Budget, Paperwork Reduction Project, Washington, DC 20503, telephone (202) 395–7340.

Title: Generic Clearance for Measurement of Client Satisfaction with National Biological Service Products and Services

Abstract: The National Biological Service (NBS) is initiating a process with standard form to gather information about its customers' level of satisfaction with its products and services. When certain NBS products and services are delivered to a client, the client will also be given a Client Response sheet on which the client is invited to rate his/her satisfaction with the product or service and offer any additional comments he/she wishes to make. The information from the responses will be summarized annually and the results used to improve NBS products and services. Copies of the final report of the summarized information will be provided to NBS' clients. This process and report will allow NBS to comply with Executive Order 12862 and the Government Performance and Results Act (44 U.S.C. Chapter 35)

Bureau Form Number: None

Frequency: Annually

Description of Respondents: Federal government officials and secondarily state and local government officials engaged in policy making, regulation, or management of public trust lands and resources

Estimated Completion time per Respondent: 0.17 Hour

Individuals invited to Respond annually: 2000

Estimate annual Responses: 300

Annual Burden Hours: 50

Bureau Clearance Officer: Don Minnich, (202) 482–4838

Dated: June 23, 1995.

F. Eugene Hester,

Deputy Director.

[FR Doc. 95–16901 Filed 7–10–95; 8:45 am]

BILLING CODE 4310–DP–M

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 32681]

H. Peter Claussen and Linda C. Claussen—Continuance in Control Exemption—Georgia & Florida Railroad Co., Inc.

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: The Commission under 49 U.S.C. 10505 exempts from the prior approval requirements of 49 U.S.C. 11343, et seq., the continuance in control by H. Peter Claussen and Linda C. Claussen (the Claussens) of the Georgia & Florida Railroad Co., Inc. (G&F), upon G&F becoming a rail carrier, subject to standard labor protective conditions. The Claussens presently control Albany Bridge Company, Inc.; Gulf and Ohio Railways, Inc., which operates the Mississippi Delta Railroad and the Atlantic & Gulf Railroad; Wiregrass Central Railroad Company, Inc.; H&S Railroad Company, Inc.; Piedmont & Atlantic Railroad Co., Inc.; and Rocky Mount & Western Railroad Co., Inc. G&F filed a notice of exemption in Finance Docket No. 32680 to exempt its acquisition, lease, and