Performance Report, ''Reinventing the Regulation of Animal Drugs,'' May 1996. FDA solicited comments on all aspects of its proposed rulemaking relating to INAD and NADA regulations and requested comments on specific issues including defining ''adequate and well-controlled.''

Section 2(e) of the ADAA, enacted on October 9, 1996, directed FDA to issue, within 6 months of its enactment, proposed regulations to further define the term ''adequate and well-controlled'' to require that field investigations be designed and conducted in a scientifically sound manner, taking into account practical conditions in the field and differences between field conditions and laboratory conditions. Elsewhere in this issue of the **Federal Register**, FDA has issued a proposed rule further defining adequate and well-controlled studies. As proposed, one characteristic of an adequate and well-controlled study is that such a study, when conducted in the target animal, be conducted in compliance with good study practices. As explained in the preamble to the proposed regulation defining adequate and well-controlled studies, FDA intends to define good study practices when the agency publishes the revised INAD regulations.

FDA is reopening the comment period on the ANPRM for the sole purpose of inviting interested persons to submit comments which will give FDA guidance in developing proposed regulations defining good study practices. The agency is particularly interested in specific comments explaining which study practices, including practices such as those specified in good laboratory practices or specific practices recommended by the Center for Veterinary Medicine during the conduct studies or in guidance, could not be followed, in whole or in part, when studies are conducted under actual use conditions in field studies. These comments should include specific examples whenever possible.

Interested persons may, on or before June 9, 1997 submit to the Dockets Management Branch (address above) written comments regarding good study practices. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 29, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–11845 Filed 5–7–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. 97N–0141]

Adequate and Well-Controlled Studies for Investigational Use and Approval of New Animal Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA), as directed by the Animal Drug Availability Act of 1996 (ADAA), is publishing a proposed regulation to further define the term ''adequate and well-controlled'' to require that field investigations be designed and conducted in a scientifically sound manner. Elsewhere in this issue of the **Federal Register**, FDA is reopening docket number 96N–0411 to receive comments regarding a concept, ''good study practices,'' that is related to the definition of adequate and well-controlled studies.

DATES: Written comments by July 22, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Herman M. Schoenemann, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1638.

SUPPLEMENTARY INFORMATION:

I. Background

Congress enacted the ADAA (Pub. L. 104–250) on October 9, 1996. Section 2(e) of the ADAA directs FDA to issue, within 6 months of its enactment, proposed regulations to further define the term ''adequate and well-controlled'' to require that field investigations be designed and conducted in a scientifically sound manner, taking into account practical conditions in the field and differences between field conditions and laboratory conditions. Although FDA believes that the definition of adequate and well-controlled is meaningful only when considered within the context of the entire set of regulations that govern the investigational use and approval of new animal drugs, FDA is publishing this proposed definition of adequate and well-controlled studies separately because of the statutory timeframe set forth in the ADAA. FDA intends to issue proposed revised investigational use new animal drug (INAD) regulations followed by proposed revised regulations governing new animal drug applications. These proposals, intended to further implement the ADAA and the Center for Veterinary Medicine's (CVM) commitment to reinvent the animal drug approval process and facilitate the approval of new animal drugs, will give context to the definition of adequate and well-controlled studies.

II. Adequate and Well-Controlled Studies

FDA has long considered that the characteristics embodied in 21 CFR 314.126 and § 514.111(a)(5)(ii) (21 CFR 514.111(a)(5)(ii)) are the essentials of an adequate and well-controlled study. Discussions held between FDA and members of the Coalition for Animal Health (Coalition) prior to enactment of the ADAA and comments from the Animal Health Institute in response to the advance notice of proposed rulemaking published November 21, 1996 (61 FR 59209), made it clear that some members of the regulated industry are concerned that certain scientific principles and practices may be difficult to apply in testing new animal drugs under field conditions. In response, FDA evaluated the extent to which the characteristics in § 514.111(a)(5)(ii) represent sound scientific principles essential for adequate and well-controlled studies. After careful consideration of the characteristics in light of the concerns expressed, FDA believes that the characteristics set forth in § 514.111(a)(5)(ii), with minor modifications, remain sound scientific principles essential for all adequate and well-controlled studies whether conducted under laboratory or field conditions. (See definition of substantial evidence, section 512(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(d)(3))). The agency is proposing to replace current § 514.111(a)(5)(ii) with new proposed § 514.117, which contains minor revisions to the current regulation on adequate and well-controlled studies.

The primary purpose of conducting adequate and well-controlled studies is, and has always been, to distinguish the effect of the drug from other influences, such as spontaneous change in the

course of disease and biased observation, so that a determination can be made whether the drug is effective. Thus, FDA's objectives in defining adequate and well-controlled studies remain unchanged. In the **Federal Register** of February 22, 1985 (50 FR 7452), FDA stated that the regulation defining adequate and well-controlled studies has two primary objectives: ''(1) to allow the agency to assess methods for minimizing bias; and (2) to assure a sufficiently detailed description of the study to allow scientific assessment and interpretation of it.'' These principles continue to apply whether a study is conducted on a drug intended for use in animals or humans or whether the study is conducted under laboratory or field conditions.

To satisfy the objective of minimizing bias, the use of appropriate controls in a study design is of critical importance. Therefore, proposed § 514.117(b)(4) lists the acceptable types of controls that may be used when conducting adequate and well-controlled studies. FDA has listed the types of controls in descending order—roughly in accordance with the ease of interpretation of associated studies. FDA believes that there may be good reasons for using different types of controls in study designs for particular situations and that the regulation is sufficiently flexible to accommodate the needs of sponsors in this respect. As a matter of past practice, FDA has approved products whose effectiveness was established on the basis of studies utilizing each of the controls listed in the proposed definition of adequate and well-controlled studies.

The sponsor's choice of the type of control used in a study should be based on the scientific, ethical, and practical circumstances associated with that particular study. This decision should integrate, among other considerations, information such as the claim being made for the drug, the nature of the new animal drug, the animal population for which the animal drug is intended, and the number of animals necessary to demonstrate effectiveness. As long as the sponsor's choice is scientifically justifiable and the studies are properly designed and conducted, the approvability of the application will not be affected by the choice of control. Nothing in the proposed regulation prohibits an animal from serving as its own control under such circumstances. Sponsors are encouraged to discuss the choice of control and other aspects of study design with CVM during the development of the protocol.

In proposed § 514.117(b)(4)(iii), FDA has modified the description of the active treatment concurrent control in the current § 514.111(a)(5)(i)(*a*)(*4*)(*iii*) to make it consistent with such descriptions used elsewhere in the regulations. A demonstration of effectiveness by means of showing similarity of the new animal drug to an active control drug is an indirect demonstration of effectiveness because the active control treatment serves as an intermediary in the comparison between the new animal drug and the placebo. That is, it is presumed, without actually measuring it, that the active control would have been superior to the placebo if there had been a comparison between the active control and placebo. Under this study design, similarity of the new animal drug and active control drug can mean either that both were effective or that neither was effective. Therefore, FDA has specified that the analysis of the study must explain why the active control drug should be considered to have been effective in the completed study, for example, by reference to previous placebo-controlled studies of the active control drug. Although the active treatment concurrent control may be useful in studies where humane considerations are presumed paramount, a sponsor needs to carefully consider, based on the particular circumstances associated with a study, whether the use of an active treatment concurrent control (due to the greater number of animals often necessary to demonstrate effectiveness in an active control study) may be less humane than other controls. For example, use of an active control may require inducing a disease or condition in a greater number of animals than would be necessary with other types of controls and animals in the test (or control) group may suffer if the new animal drug (or control article) proves to be unsafe or ineffective.

Consistent with the objective of the regulation on adequate and well-controlled studies to assure that there is a sufficiently detailed description of studies to allow proper scientific assessment and interpretation, the proposed definition of adequate and well-controlled studies states in § 514.117(b)(2) that good study practices are to be followed in conducting such studies in the target animal species. An application for a new animal drug approval will, with respect to each study conducted in the target animal species, need to include a statement that the study was conducted in compliance with good study practices. Minor, inconsequential deviations from good study practices would not lead to the conclusion that the study did not comply with good study practices; rather, substantial compliance with good study practices would be considered compliance. FDA intends to establish this set of study standards when the agency proposes revisions to its INAD regulations; until regulations defining good study practices are finalized, the study report for an adequate and well-controlled study need not contain a statement describing adherence to good study practices. FDA intends to publish, as soon as possible, the revised INAD regulations, including the requirements of good study practices. The agency published in the **Federal Register** an advance notice of proposed rulemaking soliciting comments regarding proposed revisions to the INAD regulations and specifically requesting comments on defining ''adequate and well-controlled'' (61 FR 59209). FDA is reopening elsewhere in this issue of the **Federal Register** docket number 96N–0411 to receive comments specifically related to defining good study practices. The agency encourages interested parties to submit comments regarding good study practices to that docket and is considering additional forums in which interested parties can provide comments and discuss with FDA the general concepts of these regulations. In the interim, the clear reference in the proposed definition of adequate and well-controlled studies to a standard of conduct specifically designed for target animal studies, good study practices, should clear up any confusion that sponsors may have regarding the need to apply good laboratory practices to the conduct of field studies. It is the agency's intent that the referenced standard of conduct should be applied with sound scientific judgment. A study that is designed and conducted in a manner that is consistent with sound scientific principles and practices would generally not be rejected because of minor, inconsequential deviations from good study practices.

Proposed § 514.117 continues to anticipate that there may be limited circumstances in which a scientifically sound evaluation of a particular study is not precluded by certain flaws in the protocol for, or execution of, the study and provides for a procedure to seek a waiver from particular characteristics enumerated in the definition. However, because FDA believes that the agency's description of adequate and well-controlled studies has served satisfactorily as a basis for approval over time and contains the essential characteristics of such studies, FDA

concludes that any request for a waiver must be well-justified.

All studies intended by the sponsor to be used to support an approval, including adequate and well-controlled studies to demonstrate effectiveness, must be designed, conducted, and reported in a manner which provides assurance that the study report and the underlying data are reliable and can be appropriately reviewed. Without such reliable data and information the agency cannot make the safety, effectiveness, and labeling determinations required for approval under the statue (See 21 U.S.C. 360b(d).) FDA believes that generation of reliable data and information can best be accomplished by conducting adequate and well-controlled studies under a documented program of quality assurance.

The primary purpose of adequate and well-controlled studies is to determine whether the animal drug is effective. Therefore, adequate and well-controlled field studies must balance the need to control environmental and other factors with the need to observe the effects of the animal drug under closely approximated use conditions so that the true effect of the animal drug can be measured and an appropriate inference can be drawn regarding the effect of the animal drug in actual use. In general, as long as a study reflects a considered judgment regarding the study's appropriateness relative to particular scientific, ethical, and practical circumstances and the study is properly designed and conducted (e.g., it uses an appropriate control group, minimizes bias, and assures a sufficiently detailed description of the study to allow the application of a documented quality assurance process and subsequent scientific assessment and interpretation), the study will be considered by FDA in support of approval of an application.

III. Environmental Impact

FDA has carefully considered the potential environmental impacts of this proposed rule. The agency has determined under 21 CFR 25.24(a)(8) 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.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and under the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

Section 2(e) of the ADAA requires FDA to further define the term ''adequate and well-controlled'' to require that field investigations be designed and conducted in a scientifically sound manner, taking into account practical conditions in the field and differences between field conditions and laboratory conditions. Discussions between FDA and regulated industry during the development of the ADAA made it clear that the regulated industry is concerned that certain scientific principles and practices may be difficult to apply in testing new animal drugs under actual field conditions. FDA reviewed the essentials of adequate and well-controlled studies currently identified in § 514.111(a)(5)(ii) and determined that these essentials continue to represent scientifically sound principles governing the conduct of adequate and well-controlled studies, whether conducted under laboratory or field conditions. However, FDA does agree that the practices followed in the conduct of adequate and well-controlled studies in the target animal under field conditions may need to be more flexible in some regards than the practices followed under laboratory conditions. Thus, the primary change in FDA's proposed definition of adequate and well-controlled studies is the definitions requirement that an adequate and well-control study conducted in the target animal be conducted in compliance with good study practices.

The definition of adequate and well-controlled studies in proposed § 514.117 has significance only within the context of the regulations governing investigational use and approval of new animal drugs. Because FDA has not issued revised INAD regulations to fully define good study practices and has not issued revised new animal drug application regulations, there will be little or no effect from this proposed rule on the level of effort currently expended by industry in testing the effectiveness of new animal drugs as part of the drug approval process. A thorough economic analysis will be conducted on the impact of proposed changes to the regulations governing INAD's, including provisions defining good study practices, and on the impact of proposed changes to the new animal drug application regulations in future proposals.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities unless the rule is not expected to have a significant economic impact on a substantial number of small entities. As this proposed regulation will not impose significant new costs on any firms, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commissioner of Food and Drugs certifies that the final rule will not have a significant impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

V. Unfunded Mandates Act of 1995

The Unfunded Mandates Act of 1995 (2 U.S.C. 1532) requires that agencies prepare an assessment of the anticipated costs and benefits before proposing any rule that may result in annual expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation). This proposed rule does not impose any mandates on State, local, or tribal governments, or the private sector that will result in an annual expenditure of $100,000,000 or more.

Lists of Subjects in 21 CFR part 514

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR part 514 is amended as follows:

PART 514—NEW ANIMAL DRUG APPLICATIONS

1. The authority citation for 21 CFR part 514 continues to read as follows:

Authority: Secs. 501, 502, 512, 701, 721, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360b, 371, 379e, 381).

2. Section 514.111 is amended by revising paragraph (a)(5) to read as follows:

§ 514.111 Refusal to approve an application.

(a) * * *

(5) Evaluated on the basis of information submitted as part of the application and any other information before the Food and Drug Administration with respect to such drug, there is lack of substantial evidence consisting of one or more adequate and well-controlled studies by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and reasonably be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

* * * * *

3. New § 514.117 is added to subpart B to read as follows:

§ 514.117 Adequate and well-controlled studies.

(a) *Purpose*. The primary purpose of conducting adequate and well-controlled studies of a new animal drug is to distinguish the effect of the new animal drug from other influences, such as spontaneous change in the course of the disease, normal animal production performance, or biased observation. One or more adequate and well-controlled studies are required to establish, by substantial evidence, that a new animal drug is effective. The characteristics described in paragraph (b) of this section have been developed over a period of years and are generally recognized as the essentials of an adequate and well-controlled study. Well-controlled, as used in the phrase adequate and well-controlled, emphasizes an important aspect of adequacy. FDA considers these characteristics in determining whether a study is adequate and well-controlled for purposes of section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b). Reports of adequate and well-controlled studies, in addition to providing a basis for determining whether a new animal drug is effective, may also be needed to support claims of target animal safety. The report of an adequate and well-controlled study should provide sufficient details of study design, conduct, and analysis to allow critical evaluation and a determination of whether the characteristics of an adequate and well-controlled study are present.

(b) *Characteristics*. An adequate and well-controlled study has the following characteristics:

(1) The protocol for the study (protocol) and the report of the study results (study report) must include a clear statement of the study objective(s).

(2) Any study conducted in the target animal shall be conducted in compliance with the good study practices. The protocol contains a statement acknowledging the applicability of, and intention to follow, the good study practices for the conduct of the study. The study report contains a statement describing adherence to the good study practices.

(3) The study is conducted with a new animal drug that is produced in accordance with appropriate manufacturing practices, which include, but are not necessarily limited to, the manufacture, processing, packaging, holding, and labeling of the new animal drug such that the critical characteristics of identity, strength, quality, purity, and physical form of the new animal drug are known, recorded, and reproducible, to permit meaningful evaluations of and comparisons with other studies conducted with the new animal drug. The physical form of a new animal drug includes the formulation and physical characterization (including delivery systems thereof, if any) of the new animal drug as presented to the animal. The protocol and study report must include an identification number which can be correlated with the specific formulation and production process used to manufacture the new animal drug used in the study.

(4) The study uses a design that permits a valid comparison with one or more controls to provide a quantitative evaluation of drug effects. The protocol and the study report must describe the precise nature of the study design, e.g., duration of treatment periods, whether treatments are parallel, sequential, or crossover, and the determination of sample size. Within the broad range of studies conducted to support a determination of the effectiveness of a new animal drug, certain of the controls listed below would be appropriate and preferred depending on the study conducted:

(i) *Placebo concurrent control*. The new animal drug is compared with an inactive preparation designed to resemble the new animal drug as far as possible.

(ii) *Untreated concurrent control*. The new animal drug is compared with the absence of any treatment. The use of this control may be appropriate when objective measurements of effectiveness, not subject to observer bias, are available.

(iii) *Active treatment concurrent control*. The new animal drug is compared with known effective therapy. The use of this control is appropriate when the use of a placebo control or of an untreated concurrent control would unreasonably compromise the welfare of the animals. Similarity of the new animal drug and the active control drug can mean either that both drugs were effective or that neither was effective. The study report should assess the ability of the study to have detected a difference between treatments. The evaluation of the study should explain why the new animal drugs should be considered effective in the study, for example, by reference to results in previous placebo-controlled studies of the active control.

(iv) *Historical control*. The results of treatment with the new animal drug are quantitatively compared with experience historically derived from the adequately documented natural history of the disease or condition, or with a regimen (therapeutic, diagnostic, prophylactic) whose effectiveness is established, in comparable animals. Because historical control populations usually cannot be as well assessed with respect to pertinent variables as can concurrent control populations, historical control designs are usually reserved for special circumstances. Examples include studies in which the effect of the new animal drug is self-evident or studies of diseases with high and predictable mortality, or signs and symptoms of predictable duration or severity, or, in the case of prophylaxis, predictable morbidity.

(5) The study uses a method of selecting animals that provides adequate assurances that the animals are suitable for the purposes of the study. For example, the animals can reasonably be expected to have animal production characteristics typical of the class(es) of animals for which the new animal drug is intended, there is adequate assurance that the animals have the disease or condition being studied, or, in the case of prophylactic agents, evidence of susceptibility and exposure to the condition against which prophylaxis is desired has been provided. The protocol and the study report describe the method of selecting animals for the study.

(6) The study uses a method to assign a treatment or a control to each experimental unit of animals that is random and minimizes bias. Experimental units of animals are groups of animals that are comparable with respect to pertinent variables such as age, sex, class of animal, severity of disease, duration of disease, dietary regimen, level of animal production, and use of drugs or therapy other than the new animal drug. The protocol and the study report describe the method of

assignment of animals to an experimental unit to account for pertinent variables and method of assignment of a treatment or a control to the experimental units. When the effect of such variables is accounted for by an appropriate design, and when, within the same animal, effects due to the test drug can be obtained free of the effects of such variables, the same animal may be used for both the test drug and the control using the controls set forth in paragraph (b)(4) of this section.

(7) The study uses methods to minimize bias on the part of observers and analysts of the data that are adequate to prevent undue influences on the results and interpretation of the study data. The protocol and study report explain the methods of observation and recording of the animal response variables and document the methods, such as ''blinding'' or ''masking,'' used in the study for excluding or minimizing bias in the observations.

(8) The study uses methods to assess animal response that are well-defined and reliable. The protocol and study report describe the methods for conducting the study, including any appropriate analytical and statistical methods, used to collect and analyze the data resulting from the conduct of the study, describe the criteria used to assess response, and, when appropriate, justify the selection of the methods to assess animal response.

(9) There is an analysis and evaluation of the results of the study in accord with the protocol adequate to assess the effects of the new animal drug. The study report evaluates the methods used to conduct, and presents and evaluates the results of, the study as to their adequacy to assess the effects of the new animal drug. This evaluation of the results of the study assesses, among other items, the comparability of treatment and control groups with respect to pertinent variables and the effects of any interim analyses performed.

(c) *Waiver.* The Director of the Center for Veterinary Medicine (the Director) may, on the Director's own initiative or on the petition of an interested person, waive in whole or in part any of the criteria in paragraph (b) of this section with respect to a specific study. A petition for a waiver is required to set forth clearly and concisely the specific criteria from which waiver is sought, why the criteria are not reasonably applicable to the particular study, what alternative procedures, if any, are to be, or have been employed, and what results have been obtained. The petition is also required to state why the studies so conducted will yield, or have yielded, substantial evidence of effectiveness, notwithstanding nonconformance with the criteria for which waiver is requested.

(d) *Uncontrolled studies.* Uncontrolled studies or partially controlled studies, including studies for which the Director has granted a waiver, under paragraph (c) of this section, of the use of any necessary control described in paragraph (b)(4) of this section, are not acceptable as the sole basis for the approval of claims of effectiveness or target animal safety. Such studies, carefully conducted and documented, may provide corroborative support of adequate and well-controlled studies regarding effectiveness and may yield valuable data regarding safety of the new animal drug. Such studies will be considered on their merits in the light of the characteristics listed here. Isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered.

Dated: April 29, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–11846 Filed 5–7–97; 8:45 am]

BILLING CODE 4160–01–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Chapter I

[CC Docket No. 95–116; DA 97–916]

The North American Numbering Council (NANC) Issues Recommendations Regarding the Implementation of Telephone Number Portability

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission has released a Public Notice which establishes a pleading cycle for comments on the NANC's recommendations regarding local number portability administrators (LPNAs), the duties of LPNAs, the location of regional number portability databases, and technical specifications for the regional databases.

DATES: Comments are due on or before June 2, 1997, and reply comments are due on or before June 17, 1997.

ADDRESSES: Comments and reply comments should be sent to Office of the Secretary, Federal Communications Commission, 1919 M Street, NW., Room 222, Washington, D.C. 20554, with a copy to Janice Myles of the Common Carrier Bureau, 1919 M Street, NW., Room 544, Washington, D.C. 20554. Parties should also file one copy of any documents filed in this docket with the Commission's copy contractor, International Transcription Services, Inc., 2100 M Street, NW., Suite 140, Washington, D.C. 20037.

FOR FURTHER INFORMATION CONTACT: Steven Teplitz or Kyle Dixon, Policy and Program Planning Division, Common Carrier Bureau, (202) 418–1580.

SUPPLEMENTARY INFORMATION:

Synopsis of Public Notice

On June 27, 1996, the Commission adopted the *First Report and Order and Further Notice of Proposed Rulemaking* (*First Report & Order*) (61 FR 38605 (July 25, 1996)) in the above-referenced docket implementing the requirement under section 251(b) of the Communications Act of 1934, as amended, that all local exchange carriers offer number portability in accordance with requirements prescribed by the Commission. In the *First Report & Order*, the Commission directed the North American Numbering Council (NANC), a federal advisory committee, to select one or more independent, non-governmental entities that are not aligned with any particular telecommunications segment, to serve as a local number portability administrator(s) (LNPA(s)). The Commission also directed the NANC to make recommendations regarding, *inter alia*, the duties of LNPA(s), the location of regional databases, and technical specifications for the regional databases.

The NANC forwarded its recommendations to the Commission on May 1, 1997 in a report from its Local Number Portability Administration Selection Working Group, dated April 25, 1997. Specifically, the NANC issued recommendations in the following areas: (1) What party or parties should be selected as LNPA(s); (2) whether one or multiple LNPA(s) should be selected; (3) how the LNPA(s) should be selected; (4) specific duties of the LNPA(s); (5) geographic coverage of the regional databases; (6) technical standards, including interoperability standards, network interface standards, and technical specifications, for the regional databases; (7) the sharing of numbering information between the North American Numbering Plan Administrator and the LNPA(s); and (8) the future role of the NANC with respect to local number portability issues. The Commission will act on these recommendations in a future order.