read-only formats in all cases; each agency receiving unit retains the flexibility to determine whatever format is most suitable. Those intending to submit material are expected to consult with the appropriate agency receiving unit to determine the acceptable formats.

Although FDA access to electronic records on open systems maintained by firms is not anticipated in the near future, the agency believes it would be inappropriate to rule out such a procedure. Such access can be a valuable inspection tool and can enhance efficiencies by reducing the time investigators may need to be on site. The agency believes it is important to develop appropriate procedures and security measures in cooperation with industry to ensure that such access does not jeopardize data confidentiality or integrity.

I. Effective Date/Grandfathering

9. Several comments addressed the proposed effective date of the final rule, 90 days after publication in the Federal Register, and suggested potential exemptions (grandfathering) for systems now in use. Two comments requested an expedited effective date for the final rule. One comment requested an effective date at least 18 months after publication of the final rule to permit firms to modify and validate their systems. One comment expressed concern about how the rule, in general, will affect current systems, and suggested that the agency permit firms to continue to use existing electronic record systems that otherwise conform to good manufacturing or laboratory practices until these firms make major modifications to those systems or until 5 years have elapsed, whichever comes first. Several other comments requested grandfathering for specific sections of the proposed rule.

The agency has carefully considered the comments and suggestions regarding the final rule's effective date and has concluded that the effective date should be 5 months after date of publication in the Federal Register. The agency wishes to accommodate firms that are prepared now to comply with part 11 or will be prepared soon, so as to encourage and foster new technologies in a manner that ensures that electronic record and electronic signature systems are reliable, trustworthy, and compatible with FDA's responsibility to promote and protect public health. The agency believes that firms that have consulted with FDA before adopting new electronic record and electronic signature technologies (especially technologies that may impact on the ability of the agency to conduct its work effectively) will need to make few, if any, changes to systems used to maintain records required by FDA.

The agency believes that the provisions of part 11 represent minimal standards and that a general exemption for existing systems that do not meet these provisions would be inappropriate and not in the public interest because such systems are likely to generate electronic records and electronic signatures that are unreliable, untrustworthy, and not compatible with FDA's responsibility to promote and protect public health. Such an exemption might, for example, mean that a firm could: (1) Deny FDA inspectional access to electronic record systems, (2) permit unauthorized access to those systems, (3) permit individuals to share identification codes and passwords, (4) permit systems to go unvalidated, and (5) permit records to be falsified in many ways and in a manner that goes undetected.

The agency emphasizes that these regulations do not require, but rather permit, the use of electronic records and signatures. Firms not confident that their electronic systems meet the minimal requirements of these regulations are free to continue to use traditional signatures and paper documents to meet recordkeeping requirements.

J. Comments by Electronic Mail (e-mail) and Electronic Distribution of FDA Documents

10. One comment specifically noted that the agency has accepted comments by e-mail and that this provides an additional avenue for public participation in the rulemaking process. Another comment encouraged FDA to expand the use of electronic media to provide information by such open systems as bulletin boards.

The agency intends to explore further the possibility of continuing to accept public comments by e-mail and other electronic means. For this current experiment, the agency received only one comment by e-mail. The comment that addressed this issue was, itself, transmitted in a letter. The agency recognizes the benefits of distributing information electronically, has expanded that activity, and intends to continue that expansion. Although only one e-mail comment was received, the agency does not attribute that low number to a lack of ability to send e-mail because the agency received e-mail from 198 persons who requested the text of the proposed rule, including requests from people outside the United States.

K. Submissions by Facsimile (Fax)

11. One comment said that part 11 should include a provision for FDA acceptance of submissions by fax, such as import form FDA 2877. The comment noted that the U.S. Customs Service accepts fax signatures on its documents, and claimed that FDA's insistence on hard copies of form FDA 2877 is an impediment to imports.

The agency advises that part 11 permits the unit that handles import form FDA 2877 to accept that record in electronic form when it is prepared logistically to do so. As noted in the discussion on § 11.1(b) in comment 21 of this document, the agency recognizes that faxes can be in paper or electronic form, based on the capabilities of the sender and recipient.

L. Blood Bank Issues

12. Two comments addressed blood bank issues in the context of electronic records and electronic signatures and said the agency should clarify that part 11 would permit electronic crossmatching by a central blood center for individual hospitals. One comment stated that remote blood center and transfusion facilities should be permitted to rely on electronically communicated information, such as authorization for labeling/issuing units of blood, and that the electronic signature of the supervisor in the central testing facility releasing the product for labeling and issuance should be sufficient because the proposed rule guards against security and integrity problems.

One comment questioned whether, under part 11, electronic signatures would meet the signature requirements for the release of units of blood, and if there would be instances where a full signature would be required instead of a technician's identification. Another comment asserted that it is important to clarify how the term "batch" will be interpreted under part 11, and suggested that the term used in relation to blood products refers to a series of units of blood having undergone common manufacturing processes and recorded on the same computerized document. The comment contrasted this to FDA's current view that each unit of blood be considered a batch.

The agency advises that part 11 permits release records now in paper form to be in electronic form and traditional handwritten signatures to be electronic signatures. Under part 11, the name of the technician must appear in the record display or printout to clearly identify the technician. The appearance of the technician's identification code

alone would not be sufficient. The agency also advises that the definition of a "batch" for blood or other products is not affected by part 11, which addresses the trustworthiness and reliability of electronic records and electronic signatures, regardless of how a batch, which is the subject of those records and signatures, is defined.

M. Regulatory Flexibility Analysis

13. One comment said that, because part 11 will significantly impact a substantial number of small businesses, even though the impact would be beneficial, FDA is required to perform a regulatory flexibility analysis and should publish such an analysis in the Federal Register before a final rule is issued.

The comment states that the legislative history of the Regulatory Flexibility Act is clear that, "significant economic impact," as it appears at 5 U.S.C. 605(b) is neutral with respect to whether such impact is beneficial or adverse.

Contrary to the comment's assertion, the legislative history is not dispositive of this matter. It is well established that the task of statutory construction must begin with the actual language of the statute. (See *Bailey* v. *United States*, 116 S. Ct. 595, 597 (1996).) A statutory term must not be construed in isolation; a provision that may seem ambiguous in isolation is often clarified by the remainder of the statute. (See *Dept. Of Revenue of Oregon* v. *ACF Industries*, 114 S. Ct. 843, 850 (1994).) Moreover, it is a fundamental canon of statutory construction that identical terms within the same statute must bear the same meaning. (See *Reno* v. *Koray*, 115 S. Ct. 2021, 2026 (1995).)

In addition to appearing in 5 U.S.C. 605(b), the term "significant economic impact" appears elsewhere in the statute. The legislation is premised upon the congressional finding that alternative regulatory approaches may be available which "minimize the significant economic impact" of rules (5 U.S.C. 601 note). In addition, an initial regulatory flexibility analysis must describe significant regulatory alternatives that "minimize any significant economic impact" (5 U.S.C. 603(c)). Similarly, a final regulatory flexibility analysis must include a description of the steps the agency has taken to "minimize any significant economic impact" (5 U.S.C. 604(a)(5)). The term appeared as one of the elements of a final regulatory flexibility analysis, as originally enacted in 1980. (See Pub. L. No. 96-354, 3(a), 94 Stat. 1164, 1167 (1980) (formerly codified at 5 U.S.C. 604(a)(3)).) In addition, when Congress amended the elements of a final regulatory flexibility analysis in 1996, it re-enacted the term, as set forth above. (See Pub. L. 104-121, 241(b), 110 Stat. 857, 865 (1996) (codified at 5 U.S.C.604(a)(5)).)

Unless the purpose of the statute was intended to increase the economic burden of regulations by minimizing positive or beneficial effects, "significant economic impact" cannot include such effects. Because it is beyond dispute that the purpose of the statute is not increasing economic burdens, the plain meaning of "significant economic impact" is clear and necessarily excludes beneficial or positive effects of regulations. Even where there are some limited contrary indications in the statute's legislative history, it is inappropriate to resort to legislative history to cloud a statutory text that is clear on its face. (See *Ratzlaff* v. *United States*, 114 S. Ct. 655, 662 (1994).) Therefore, the agency concludes that a final regulatory flexibility analysis is not required for this regulation or any regulation for which there is no significant adverse economic impact on small entities. Notwithstanding these conclusions, FDA has nonetheless considered the impact of the rule on small entities. (See section XVI. of this document.)

N. Terminology

14. One comment addressed the agency's use of the word "ensure" throughout the rule and argued that the agency should use the word "assure" rather than "ensure" because "ensure" means "to guarantee or make certain" whereas "assure" means "to make confident." The comment added that "assure" is also more consistent with terminology in other regulations.

The agency wishes to emphasize that it does not intend the word "ensure" to represent a guarantee. The agency prefers to use the word "ensure" because it means to make certain.

O. General Comments Regarding the Prescription Drug Marketing Act of 1987 (PDMA)

15. Three comments addressed the use of handwritten signatures that are recorded electronically (SRE's) under part 11 and PDMA. One firm described its delivery information acquisition device and noted its use of time stamps to record when signatures are executed. The comments requested clarification that SRE's would be acceptable under the PDMA regulations. One comment assumed that subpart C of part 11 (Electronic Signatures) would not apply to SRE's, noting that it was not practical under PDMA (given the large number of physicians who may be eligible to receive drug product samples) to use such alternatives as identification codes combined with passwords.

The agency advises that part 11 applies to handwritten signatures recorded electronically and that such signatures and their corresponding electronic records will be acceptable for purposes of meeting PDMA's requirements when the provisions of part 11 are met. Although subpart C of part 11 does not apply to handwritten signatures recorded electronically, the agency advises that controls related to electronic records (subpart B), and the general provisions of subpart A, do apply to electronic records in the context of PDMA. The agency emphasizes, however, that part 11 does not restrict PDMA signings to SRE's, and that organizations retain the option of using electronic signatures in conformance with part 11. Furthermore, the agency believes that the number of people in a given population or organization should not be viewed as an insurmountable obstacle to use of electronic signatures. The agency is aware, for example, of efforts by the American Society of Testing and Materials to develop standards for electronic medical records in which digital signatures could theoretically be used on a large scale.

P. Comments on the Unique Nature of Passwords

16. Several comments noted, both generally and with regard to §§ 11.100(a), 11.200(a), and 11.300, that the password in an electronic signature that is composed of a combination of password and identification code is not, and need not be, unique. Two comments added that passwords may be known to system security administrators who assist people who forget passwords and requested that the rule acknowledge that passwords need not be unique. One comment said that the rule should describe how uniqueness is to be determined.

The agency acknowledges that when an electronic signature consists of a combined identification code and password, the password need not be unique. It is possible that two persons in the same organization may have the same password. However, the agency believes that where good password practices are implemented, such coincidence would be highly unlikely. As discussed in section XIII. of this document in the context of comments on proposed § 11.300, records are less trustworthy and reliable if it is relatively easy for someone to deduce or execute, by chance, a person's electronic

signature where the identification code of the signature is not confidential and the password is easily guessed.

The agency does not believe that revising proposed § 11.100(a) is necessary because what must remain unique is the electronic signature, which, in the case addressed by the comments, consists not of the password alone, but rather the password in combination with an identification code. If the combination is unique, then the electronic signature is unique.

The agency does not believe that it is necessary to describe in the regulations the various ways of determining uniqueness or achieving compliance with the requirement. Organizations thereby maintain implementation flexibility.

The agency believes that most system administrators or security managers would not need to know passwords to help people who have forgotten their own. This is because most administrators or managers have global computer account privileges to resolve such problems.

IV. Scope (§ 11.1)

17. One comment suggested adding a new paragraph to proposed § 11.1 that would exempt computer record maintenance software installed before the effective date of the final rule, and that would exempt electronic records maintained before that date. The comment argued that such exemptions were needed for economic and constitutional reasons because making changes to existing systems would be costly and because the imposition of additional requirements after the fact could be regarded as an ex post facto rule. The comment said firms have been using electronic systems that have demonstrated reliability and security for many years before the agency's publication of the ANPRM, and that the absence of FDA's objections in inspectional form FDA 483 was evidence of the agency's acceptance of the system.

As discussed in section III.I. of this document, the agency is opposed to "grandfathering" existing systems because such exemptions may perpetuate environments that provide opportunities for record falsification and impair FDA's ability to protect and promote public health. However, the agency wishes to avoid any confusion regarding the application of the provisions of part 11 to systems and electronic records in place before the rule's effective date. Important distinctions need to be made relative to an electronic record's creation, modification, and maintenance because various portions of part 11 address matters relating to these actions. Those provisions apply depending upon when a given electronic record is created, modified, or maintained.

Electronic records created before the effective date of this rule are not covered by part 11 provisions that relate to aspects of the record's creation, such as the signing of the electronic record. Those records would not, therefore, need to be altered retroactively. Regarding records that were first created before the effective date, part 11 provisions relating to modification of records, such as audit trails for record changes and the requirement that original entries not be obscured, would apply only to those modifications made on or after the rule's effective date, not to modifications made earlier. Likewise, maintenance provisions of part 11, such as measures to ensure that electronic records can be retrieved throughout their retention periods, apply to electronic records that are being maintained on or after the rule's effective date. The hardware and software, as well as operational procedures used on or after the rule's effective date, to create, modify, or maintain electronic records must comply with the provisions of part 11.

The agency does not agree with any suggestion that FDA endorsement or acceptance of an electronic record system can be inferred from the absence of objections in an inspection report. Before this rulemaking, FDA did not have established criteria by which it could determine the reliability and trustworthiness of electronic records and electronic signatures and could not sanction electronic alternatives when regulations called for signatures. A primary reason for issuing part 11 is to develop and codify such criteria. FDA will assess the acceptability of electronic records and electronic signatures created prior to the effective date of part 11 on a case-by-case basis.

18. One comment suggested that proposed § 11.1 exempt production of medical devices and in vitro diagnostic products on the grounds that the subject was already adequately addressed in the medical device CGMP regulations currently in effect in § 820.195 (21 CFR 820.195), and that additional regulations would be confusing and would limit compliance.

The agency believes that part 11 complements, and is supportive of, the medical device CGMP regulations and the new medical device quality system regulation, as well as other regulations, and that compliance with one does not confound compliance with others. Before publication of the ANPRM, the agency determined that existing regulations, including the medical device CGMP regulations, did not adequately address electronic records and electronic signatures. That determination was reinforced in the comments to the ANPRM, which focused on the need to identify what makes electronic records reliable, trustworthy, and compatible with FDA's responsibility to promote and protect public health. For example, the provision cited by the comment, § 820.195, states "When automated data processing is used for manufacturing or quality assurance purposes, adequate checks shall be designed and implemented to prevent inaccurate data output, input, and programming errors." This section does not address the many issues addressed by part 11, such as electronic signatures, record falsification, or FDA access to electronic records. The relationship between the quality system regulation and part 11 is discussed at various points in the preamble to the quality system regulation.

19. One comment asserted that for purposes of PDMA, the scope of proposed part 11 should be limited to require only those controls for assessing signatures in paper-based systems because physicians' handwritten signatures are executed to electronic records. The comment further asserted that, because drug manufacturers' representatives carry computers into physicians' offices (where the physicians then sign sample requests and receipts), only closed system controls should be needed.

The agency believes that, for purposes of PDMA, controls needed for electronic records bearing handwritten signatures are no different from controls needed for the same kinds of records and signatures used elsewhere, and that proposed § 11.1 need not make any such distinction.

In addition, the agency disagrees with the implication that all PDMA electronic records are, in fact, handled within closed systems. The classification of a system as open or closed in a particular situation depends on what is done in that situation. For example, the agency agrees that a closed system exists where a drug producer's representative (the person responsible for the content of the electronic record) has control over access to the electronic record system by virtue of possessing the portable computer and controlling who may use the computer to sign electronic records. However, should the firm's representative transfer copies of those records to a public online service that stores them for the drug firm's

subsequent retrieval, the agency considers such transfer and storage to be within an open system because access to the system holding the records is controlled by the online service, which is not responsible for the record's content. Activities in the first example would be subject to closed system controls and activities in the second example would be subject to open system controls.

20. One comment urged that proposed § 11.1 contain a clear statement of what precedence certain provisions of part 11 have over other regulations.

The agency believes that such statements are found in § 11.1(c):

> Where electronic signatures and their associated records meet the requirements of this part, the agency will consider the electronic signatures to be equivalent to full handwritten signatures, initials, and other general signings as required under agency regulations unless specifically excepted by regulations * * *.

and § 11.1(d) ("Electronic records that meet the requirements of this part may be used in lieu of paper records, in accordance with § 11.2, unless paper records are specifically required."). These provisions clearly address the precedence of part 11 and the equivalence of electronic records and electronic signatures.

To further clarify the scope of the rule, FDA has revised § 11.1 to apply to electronic records submitted to the agency under requirements of the Federal Food, Drug, and Cosmetic Act (the act) and the Public Health Service Act (the PHS Act). This clarifies the point that submissions required by these statutes, but not specifically mentioned in the Code of Federal Regulations (CFR), are subject to part 11.

21. Proposed § 11.1(b) stated that the regulations would apply to records in electronic form that are created, modified, maintained, or transmitted, under any records requirements set forth in Chapter I of Title 21. One comment suggested that the word "transmitted" be deleted from proposed § 11.1(b) because the wording would inappropriately apply to paper documents that are transmitted by fax. The comment noted that if the records are in machine readable form before or after transmission, they would still be covered by the revised wording.

The agency does not intend part 11 to apply to paper records even if such records are transmitted or received by fax. The agency notes that the records transmitted by fax may be in electronic form at the sender, the recipient, or both. Part 11 would apply whenever the record is in electronic form. To remedy the problem noted by the comment, the agency has added a sentence to § 11.1(b) stating that part 11 does not apply to paper records that are, or have been, transmitted by electronic means.

22. One comment asked whether paper records created by computer would be subject to proposed part 11. The comment cited, as an example, the situation in which a computer system collects toxicology data that are printed out and maintained as "raw data."

Part 11 is intended to apply to systems that create and maintain electronic records under FDA's requirements in Chapter I of Title 21, even though some of those electronic records may be printed on paper at certain times. The key to determining part 11 applicability, under § 11.1(b), is the nature of the system used to create, modify, and maintain records, as well as the nature of the records themselves.

Part 11 is not intended to apply to computer systems that are merely incidental to the creation of paper records that are subsequently maintained in traditional paper-based systems. In such cases, the computer systems would function essentially like manual typewriters or pens and any signatures would be traditional handwritten signatures. Record storage and retrieval would be of the traditional "file cabinet" variety. More importantly, overall reliability, trustworthiness, and FDA's ability to access the records would derive primarily from well-established and generally accepted procedures and controls for paper records. For example, if a person were to use word processing software to generate a paper submission to FDA, part 11 would not apply to the computer system used to generate the submission, even though, technically speaking, an electronic record was initially created and then printed on paper.

When records intended to meet regulatory requirements are in electronic form, part 11 would apply to all the relevant aspects of managing those records (including their creation, signing, modification, storage, access, and retrieval). Thus, the software and hardware used to create records that are retained in electronic form for purposes of meeting the regulations would be subject to part 11.

Regarding the comment about "raw data," the agency notes that specific requirements in existing regulations may affect the particular records at issue, regardless of the form such records take. For example, "raw data," in the context of the good laboratory practices regulations (21 CFR part 58), include computer printouts from automated instruments as well as the same data recorded on magnetic media. In addition, regulations that cover data acquisition systems generally include requirements intended to ensure the trustworthiness and reliability of the collected data.

23. Several comments on proposed § 11.1(b) suggested that the phrase "or archived and retrieved" be added to paragraph (b) to reflect more accurately a record's lifecycle.

The agency intended that record archiving and retrieval would be part of record maintenance, and therefore already covered by § 11.1(b). However, for added clarity, the agency has revised § 11.1(b) to add "archived and retrieved."

24. One comment suggested that, in describing what electronic records are within the scope of part 11, proposed § 11.1(b) should be revised by substituting "processed" for "modified" and "communicated" for "transmitted" because "communicated" reflects the fact that the information was dispatched and also received. The comment also suggested substituting "retained" for "maintained," or adding the word "retained," because "maintain" does not necessarily convey the retention requirement.

The agency disagrees. The word "modified" better describes the agency's intent regarding changes to a record; the word "processed" does not necessarily infer a change to a record. FDA believes "transmitted" is preferable to "communicated" because "communicated" might infer that controls to ensure integrity and authenticity hinge on whether the intended recipient actually received the record. Also, as discussed in comment 22 of this document, the agency intends for the term "maintain" to include records retention.

25. Two comments suggested that proposed § 11.1(b) explicitly state that part 11 supersedes all references to handwritten signatures in 21 CFR parts 211 through 226 that pertain to a drug, and in 21 CFR parts 600 through 680 that pertain to biological products for human use. The comments stated that the revision should clarify coverage and permit blood centers and transfusion services to take full advantage of electronic systems that provide process controls.

The agency does not agree that the revision is necessary because, under § 11.1(b) and (c), part 11 permits electronic records or submissions under all FDA regulations in Chapter I of Title 21 unless specifically excepted by future regulations.

26. Several comments expressed concern that the proposed rule had inappropriately been expanded in scope

from the ANPRM to address electronic records as well as electronic signatures. One comment argued that the scope of part 11 should be restricted only to those records that are currently required to be signed, witnessed, or initialed, and that the agency should not require electronic records to contain electronic signatures where the corresponding paper records are not required to be signed.

The agency disagrees with the assertion that part 11 should address only electronic signatures and not electronic records for several reasons. First, based on comments on the ANPRM, the agency is convinced that the reliability and trustworthiness of electronic signatures depend in large measure on the reliability and trustworthiness of the underlying electronic records. Second, the agency has concluded that electronic records, like paper records, need to be trustworthy, reliable, and compatible with FDA's responsibility to promote and protect public health regardless of whether they are signed. In addition, records falsification is an issue with respect to both signed and unsigned records. Therefore, the agency concludes that although the ANPRM focused primarily on electronic signatures, expansion of the subject to electronic records in the proposed rule was fully justified.

The agency stresses that part 11 does not require that any given electronic record be signed at all. The requirement that any record bear a signature is contained in the regulation that mandates the basic record itself. Where records are signed, however, by virtue of meeting a signature requirement or otherwise, part 11 addresses controls and procedures intended to help ensure the reliability and trustworthiness of those signatures.

27. Three comments asked if there were any regulations, including CGMP regulations, that might be excepted from part 11 and requested that the agency identify such regulations.

FDA, at this time, has not identified any current regulations that are specifically excepted from part 11. However, the agency believes it is prudent to provide for such exceptions should they become necessary in the future. It is possible that, as the agency's experience with part 11 increases, certain records may need to be limited to paper if there are problems with the electronic versions of such records.

28. One comment requested clarification of the meaning of the term "general signings" in proposed § 11.1(c), and said that the distinction between "full handwritten" signatures and "initials" is unnecessary because handwritten includes initials in all common definitions of handwritten signature. The comment also suggested changing the term "equivalent" to "at least equivalent" because electronic signatures are not precise equivalents of handwritten signatures and computer-based signatures have the potential of being more secure.

The agency advises that current regulations that require records to be signed express those requirements in different ways depending upon the agency's intent and expectations. Some regulations expressly state that records must be signed using "full handwritten" signatures, whereas other regulations state that records must be "signed or initialed;" still other regulations implicitly call for some kind of signing by virtue of requiring record approvals or endorsements. This last broad category is addressed by the term "general signings" in § 11.1(c).

Where the language is explicit in the regulations, the means of meeting the requirement are correspondingly precise. Therefore, where a regulation states that a signature must be recorded as "full handwritten," the use of initials is not an acceptable substitute. Furthermore, under part 11, for an electronic signature to be acceptable in place of any of these signings, the agency only needs to consider them as equivalent; electronic signatures need not be superior to those other signings to be acceptable.

29. Several comments requested clarification of which FDA records are required to be in paper form, and urged the agency to allow and promote the use of electronic records in all cases. One comment suggested that proposed § 11.1(d) be revised to read, in part, "* * * unless the use of electronic records is specifically prohibited."

The agency intends to permit the use of electronic records required to be maintained but not submitted to the agency (as noted in § 11.2(a)) provided that the requirements of part 11 are met and paper records are not specifically required. The agency also wishes to encourage electronic submissions, but is limited by logistic and resource constraints. The agency is unaware of "maintenance records" that are currently explicitly required to be in paper form (explicit mention of paper is generally unnecessary because, at the time most regulations were prepared, only paper-based technologies were in use) but is providing for that possibility in the future. For purposes of part 11, the agency will not consider that a regulation requires "maintenance" records to be in paper form where the regulation is silent on the form the record must take. FDA believes that the comments' suggested wording does not offer sufficient advantages to adopt the change.

However, to enable FDA to accept as many electronic submissions as possible, the agency is amending § 11.1(b) to include those submissions that the act and the PHS Act specifically require, even though such submissions may not be identified in agency regulations. An example of such records is premarket submissions for Class I and Class II medical devices, required by section 510(k) of the act (21 U.S.C. 360(k)).

30. Several comments addressed various aspects of the proposed requirement under § 11.1(e) regarding FDA inspection of electronic record systems. Several comments objected to the proposal as being too broad and going beyond the agency's legal inspectional authority. One comment stated that access inferred by such inspection may include proprietary financial and sales data to which FDA is not entitled. Another comment suggested adding the word "authorized" before "inspection." Some comments suggested revising proposed § 11.1(e) to limit FDA inspection only to the electronic records and electronic signatures themselves, thus excluding inspection of hardware and software used to manage those records and signatures. Other comments interpreted proposed § 11.1(e) as requiring them to keep supplanted or retired hardware and software to enable FDA inspection of those outdated systems.

The agency advises that FDA inspections under part 11 are subject to the same legal limitations as FDA inspections under other regulations. The agency does not believe it is necessary to restate that limitation by use of the suggested wording. However, within those limitations, it may be necessary to inspect hardware and software used to generate and maintain electronic records to determine if the provisions of part 11 are being met. Inspection of resulting records alone would be insufficient. For example, the agency may need to observe the use and maintenance of tokens or devices that contain or generate identification information. Likewise, to assess the adequacy of systems validation, it is generally necessary to inspect hardware that is being used to determine, among other things, if it matches the system documentation description of such hardware. The agency has concluded that hardware and software used to generate and maintain electronic records and signatures are "pertinent