

# Industry Coalition on 21 CFR Part 11

Advanced Medical Technology Association  
America's Blood Centers  
Animal Health Institute  
Consumer Healthcare Products Association  
Cosmetic, Toiletry, and Fragrance Association  
Council for Responsible Nutrition  
Council on Radionuclides and Radiopharmaceuticals  
Generic Pharmaceutical Association  
Medical Device Manufacturers Association  
National Electrical Manufacturers Association  
National Food Processors Association  
National Grain and Feed Association  
Pharmaceutical Research and Manufacturers of America

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September 17, 2004

Dockets Management Branch  
Food and Drug Administration  
HFA-305  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Dear Sir/Madam:

The Industry Coalition on 21 CFR Part 11 (the Coalition) is pleased to submit the attached Citizen Petition to the Food and Drug Administration for consideration. The Coalition comprises 13 trade associations representing manufacturers of FDA-regulated products including foods, drugs, cosmetics, veterinary drugs, and medical devices. The Coalition has had numerous discussions with FDA over the past four years as the Agency moved forward to publish guidance clarifying compliance issues in a number of different areas. This ongoing dialogue between Industry and FDA has been extremely useful not just in increasing the awareness of issues and concerns, but also as an essential element in resolving very complex issues of today and to stay current with issues created as new technology is introduced into systems and processes.

The Coalition submitted a presentation to FDA earlier this year in response to FDA's solicitation of comments on Part 11. The Coalition has advocated a risk-based approach to Part 11 compliance and believes that recently passed Federal laws should be used to support this rather than the prescriptive regulation that was promulgated several years ago. This Citizen Petition sets forth the legal reasoning.

The Coalition looks forward to the Agency's response to this petition and is prepared to answer any questions that might arise from this consideration. We look forward to a continuing discussion with FDA on areas of mutual interest.

Sincerely,



Chair, Industry Coalition on Part 11 &  
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September 17, 2004

VIA HAND DELIVERY

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Room 1061 (HFA-305)  
Rockville, MD 20852

### **CITIZEN PETITION**

The undersigned submits this petition on behalf of the Industry Coalition on 21 C.F.R. Part 11<sup>1</sup> to request that under the authority delegated by the Secretary of Health and Human Services to issue all regulations of the Food and Drug Administration (FDA), the Commissioner of Food and Drugs revoke 21 C.F.R. Part 11.

Part 11 was issued in 1997 to address important security concerns related to the use of electronic records and signatures by FDA-regulated entities. While these security concerns remain as important as ever to the protection of the public health, the prescriptive approach adopted in Part 11 has failed to adapt to changing technologies and has placed an unnecessary burden on regulated entities.

Since the Part 11 regulations were issued, Congress has enacted the Government Paperwork Elimination Act (GPEA), Pub. L. No. 105-277, Div. C., Tit. XVII, §§ 1701 *et seq.* (October 21, 1998), which requires federal agencies to accept electronic records and signatures in satisfaction of programmatic requirements. Under GPEA, the implementation of electronic record systems can be pursued under existing regulatory requirements, and does not require the issuance of separate regulatory schemes such as Part 11.

As further discussed below, the provisions of Part 11 are largely superseded by GPEA standards governing electronic records and signatures, which can be implemented through existing programmatic regulation. Part 11 should be revoked, as the public health goals that motivated issuance of Part 11 can be better realized through implementation of GPEA.

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<sup>1</sup> The members of the Industry Coalition are listed in Appendix A.

## A. *Action Requested*

The Industry Coalition requests that FDA revoke 21 C.F.R. Part 11 in its entirety, and pursue implementation of electronic record and signature systems through the application of GPEA standards and the enforcement of predicate rules.<sup>2</sup>

## B. *Statement of Grounds*

### 1. Part 11 Is Unnecessarily Burdensome and Inhibits Technological Innovation

#### a) Part 11 Goals and Framework

No specific statutory mandate triggered the issuance of the Part 11 regulations. *See* 62 Fed. Reg. 13,430, 13,464 (March 20, 1997) (final rule notice) (stating authority for issuance of Part 11 as “the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and . . . authority delegated to the Commissioner of Food and Drugs”).

Rather, Part 11 grew out of an industry initiative that was originally aimed at accommodating electronic signatures under the good manufacturing practices (GMP) regulations codified at 21 C.F.R. Parts 210 and 211. A meeting on this subject was held in 1991 between industry and FDA. FDA subsequently formed the Task Force on Electronic Identification/Signatures to develop an approach to electronic records and signatures, and in 1992, a working group of the task force recommended that FDA seek public comment via an advance notice of proposed rulemaking (ANPRM). *See* 62 Fed. Reg. 13,430. This ANPRM was issued the same year, *see* 57 Fed. Reg. 32,185 (July 21, 1992), and opened the rulemaking process that led to promulgation of Part 11. Part 11 was issued in final form in 1997. 62 Fed. Reg. 13,430.

FDA’s goal in issuing Part 11 was to provide “criteria under which FDA will consider electronic records to be equivalent to paper records, and electronic signatures equivalent to traditional handwritten signatures.” *See* 62 Fed. Reg. at *id.* To this end, Part 11 sets forth a series of specific controls applicable to systems used to “create, modify, maintain or transmit” electronic records. 21 C.F.R. § 11.10. These controls are intended to “ensure the authenticity, integrity, and, when appropriate, the confidentiality” of electronic records, and to ensure that individual signers of these records cannot repudiate their signature. *Id.* The controls listed in

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<sup>2</sup> “Predicate rules” have been characterized by FDA as “[t]he underlying requirements set forth in the [Federal Food, Drug, and Cosmetic] Act, the PHS Act, and FDA regulations (other than Part 11).” *See* FDA Guidance, *Part 11, Electronic Records; Electronic Signatures -- Scope and Application* (September 3, 2003) (FDA Part 11 Guidance) ¶ I.

§ 11.10 are applicable to electronic documents contained in both “closed systems”<sup>3</sup> and, as appropriate, “open systems.”<sup>4</sup> With regard to the latter, regulated entities are required to employ “additional measures such as document encryption and use of appropriate digital signature standards to ensure, as necessary under the circumstances, record authenticity, integrity, and confidentiality.” *Id.* § 11.30. Part 11 also contains provisions related to the linking of electronic signatures to electronic documents (“Signature manifestations,” *id.* § 11.50, and “Signature/record linking,” *id.* § 11.70), and controls specific to certain electronic signature technologies, *id.* §§ 11.100, 11.200, 11.300.

In 2003, FDA issued guidance indicating its intention to “exercise enforcement discretion” with regard to certain categories of Part 11 controls, including controls relating to validation, audit trails, record retention, record copying and inspection, and legacy systems. FDA Guidance, *Part 11, Electronic Records; Electronic Signatures -- Scope and Application* (September 3, 2003) (FDA Part 11 Guidance). A public meeting scheduled for June 11, 2004 at FDA’s initiative to “re-examine Part 11 as it applies to all FDA-regulated products,” *see* 69 Fed. Reg. 18,591 (April 8, 2004), was cancelled due to President Reagan’s funeral.

b) *Problems With The Prescriptive Approach of Part 11*

While the security concerns that motivated the issuance of Part 11 remain critical to electronic systems implementation, the Part 11 regulations themselves have not proven effective in addressing those concerns. For example, the Part 11 process controls applicable to electronic record systems prescribe specific methods for ensuring system integrity, but many of these requirements are duplicative of predicate regulation. Other Part 11 controls have required manufacturers to retain outdated systems documentation, or even the systems themselves, to comply with Part 11 inspection, audit trail and retention requirements.

In addition, a number of Part 11 controls -- including those related to electronic signatures -- are based on static technological descriptions that fail to capture the variety and innovation of available technologies. It is uncertain in many cases how these regulations apply even to existing technologies, and the need to comply with Part 11 has slowed the adoption of new technologies.

These aspects of Part 11 are not only burdensome to industry, but have also made enforcement of electronic systems security needlessly burdensome for FDA.

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<sup>3</sup> A “closed system” is defined as “an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.” 21 C.F.R. § 11.3(a)(4).

<sup>4</sup> An “open system” is defined as “an environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system.” *Id.* § 11.3(a)(9).

2. Part 11 Has Been Superseded By GPEA, Which Requires Acceptance of Electronic Records and Signatures In Satisfaction of Predicate Rule Requirements

One year after Part 11 was issued, Congress enacted the Government Paperwork Elimination Act (GPEA), which requires federal agencies to accept electronic records and electronic signatures when practicable in the “maintenance” and “submission” of documents required by federal regulation. *See* Pub. L. No. 105-277, Div. C., Tit. XVII, §§ 1704, 1707 (October 21, 1998), *codified at* 44 U.S.C. § 3504(a)(1)(B)(vi) *and* Note.

In light of GPEA, Part 11 is no longer necessary. As set forth below, GPEA applies to the same electronic record systems as Part 11, and procedures issued under GPEA address the security and integrity of those systems. The Part 11 requirements related to electronic signature technologies are largely superseded by the electronic signature provisions of GPEA. Other Part 11 requirements, such as the controls for electronic record systems listed in 21 C.F.R. § 11.10, are unnecessary when predicate rules are implemented in light of GPEA.<sup>5</sup> Overall, implementation of GPEA in conjunction with existing predicate rules will address the concerns that led to promulgation of Part 11.

a) GPEA Covers the Same Electronic Systems And Addresses the Same Security Concerns As Part 11

(1) Electronic Records and Signatures Currently Subject to Part 11 Are Covered By GPEA

By its terms, GPEA requires federal agencies to accept electronic documents and signatures in two broad categories: (1) the maintenance of records required by agency regulation, and (2) the submission of documents to the agency. GPEA §§ 1704, 1707.

Part 11 applies to the same two categories of documents. Specifically, Part 11 allows regulated parties to use electronic records and electronic signatures for (1) “records required to be maintained but not submitted to [FDA],” and (2) “records submitted to the agency” (provided the agency has identified the submission as one that can be accepted in electronic form). *See* 21 C.F.R. § 11.2(a), (b)(2).<sup>6</sup> In guidance, FDA has recently clarified the categories of documents that are subject to Part 11. *See* FDA Part 11 Guidance ¶ III.B. As clarified in the guidance, the electronic systems subject to Part 11 remain essentially the same as those set forth in the regulation: (1) “[r]ecords that are required to be maintained under predicate

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<sup>5</sup> FDA has already indicated in guidance that a number of Part 11 requirements are satisfied by compliance with analogous predicate rules. *See* FDA Part 11 Guidance ¶ III.

<sup>6</sup> FDA distinguished between these two categories so that “regulated industries [could] implement electronic records/signatures for records that are required by regulation to be maintained, but not submitted to the agency, as rapidly as possible,” while the agency continued working towards the goal of “accepting all [industry] submissions in electronic form.” *See* 59 Fed. Reg. 45,160, 45,171 (August 31, 1994) (proposed rule on Part 11).

rules,” provided they are electronic and are “relied on to perform regulated activities,” and (2) electronic records submitted to FDA under predicate rule requirements. *See id.*

Therefore, all electronic recordkeeping and submissions that are currently subject to Part 11 are also subject to GPEA.

Certain electronic records may also be subject to the Electronic Signatures in Global and National Commerce Act (E-Sign), which was enacted in 2000. *See* Pub. L. No. 106-229 §§ 101 *et seq.* (June 30, 2000), *codified at* 15 U.S.C. § 7001 *et seq.* Under E-Sign, agencies must allow the retention of commercial records in electronic form -- provided the electronic record is accurate and accessible. 15 U.S.C. § 7001(d)(1).<sup>7</sup> However, this E-Sign provision applies only to records of documents “generated in a commercial, consumer, or business transaction” -- for example, copies of private contracts that a regulated party might be required to retain. *See id.* §§ 7001(d)(1), 7006(13); *see also* OMB, *Guidance on Implementing the Electronic Signatures in Global and National Commerce Act* (September 25, 2000) (OMB E-Sign Guidance) ¶ III.B.1. Records generated “solely to comply with [government] regulations,” rather than “as part of a preexisting commercial transaction,” are subject to GPEA instead. *See* 15 U.S.C. § 7004(a), (c)(2); OMB E-Sign Guidance *at id.*

For the small subset of records held by FDA-regulated parties that may be subject to both GPEA and E-Sign, the impact of E-Sign is consistent with that of GPEA: federal agencies cannot object to retention of the documents in electronic form, provided the records are accurate and accessible. For this reason, and because GPEA applies to all electronic systems currently subject to Part 11, the remainder of this petition will analyze Part 11 requirements in light of GPEA only.

(2) OMB Procedures For GPEA Compliance Address  
Electronic Security Concerns

Under GPEA, the Office of Management and Budget (OMB) was required to develop procedures to ensure federal agencies’ acceptance of electronic documents and signatures in transactions with regulated parties. *See* GPEA §§ 1703(a), 1704. GPEA provides that

[e]lectronic records submitted or maintained in accordance with [the procedures developed by OMB], or electronic signatures or other forms of electronic authentication used in accordance with such procedures, shall not be denied legal effect, validity, or enforceability [by federal agencies] because such records are in electronic form.

*Id.* § 1707. Within five years of the enactment of GPEA -- *i.e.*, by October 21, 2003 -- federal agencies must offer “the option of electronic maintenance, submission, or disclosure of

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<sup>7</sup> This provision became effective March 1, 2001. *See* Pub. L. No. 106-229 ¶ 107(b)(1)(A).

information,” and “the use and acceptance of electronic signatures,” in accordance with the procedures issued by OMB. *Id.* § 1704.

OMB procedures for the implementation of GPEA requirements were issued in 2000. *See* OMB Memorandum M-00-10, *Implementation of the Government Paperwork Elimination Act*, 65 Fed. Reg. 25,508, 25,512 (May 2, 2000) (OMB GPEA Procedures).

As set forth in the OMB procedures, GPEA compliance requires adherence to the following principles:

- *First, agencies must adopt a risk-based approach in determining the conditions under which electronic recordkeeping and submissions will be accepted.* A variety of electronic signature technologies are available, ranging from “non-cryptographic” mechanisms using personal identification numbers (PINs) and passwords, to “cryptographic” systems such as digital signatures implemented through a public key infrastructure (PKI). *See* OMB GPEA Procedures ¶¶ II.1.b, II.7. While a system of digital signatures within a PKI is generally recognized as the most secure option, *see id.*, under GPEA “[a]gencies must strike a balance, recognizing that achieving absolute security is likely to be highly improbable in most cases and prohibitively expensive if possible.” *See id.* ¶ II.1.b. In assessing the risks associated with accepting electronic documents and signatures, agencies should employ both quantitative and qualitative assessments to assess “net benefit to the agency and the customer” and to determine the technology “most appropriate to the transaction,” so that “the level of security [is] commensurate with the level of sensitivity of the transaction.” *Id.* ¶ II.3. Agencies must weigh the costs of regulatory controls against the benefits, and to the extent agency regulations “are based on factors or circumstances that . . . no longer apply,” those rules should be revoked in favor of “a more efficient process.” *Id.* ¶ II.3.b.(4).
- *Second, agencies must ensure that any conditions placed on the acceptance of electronic recordkeeping and submissions are “compatible with standards and technology for electronic signatures that are generally used in commerce and industry.”* GPEA § 1703(b)(A); *see also* OMB GPEA Procedures ¶ I.1.<sup>8</sup> An awareness of industry standards and practices is necessary to control the “threshold costs” to regulated entities, so as to avoid “narrow[ing] the range of potential users” and “limit[ing] the benefits of electronic communications.” *Id.* ¶ II.3.b.(2).
- *Third, agencies must retain the flexibility to adapt their approaches to electronic documents and signatures as technology evolves.* *See id.* ¶ II.3.b.(3). Promulgation of regulations specifically addressed to a particular technology, or to the state of electronic-signature technology at a particular point in time, is not recommended under GPEA. Rather, OMB procedures recommend that agencies seek to accommodate electronic

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<sup>8</sup> Agencies must also avoid “inappropriately favor[ing] one industry or technology.” GPEA § 1703(b)(B).

recordkeeping and electronic signatures under existing “policies or programmatic regulations.” *See id.* ¶ II.8.a; *see also id.* ¶ I.3.a(4) (suggesting that agencies may, “if necessary,” amend regulations or policies “to remove impediments to electronic transactions”). To the extent agencies need to communicate the “terms and conditions” under which electronic documents and signatures will be accepted, OMB procedures suggest that agencies might communicate these terms and conditions in a policy document. *Id.* ¶ II.8.b. While the option of issuing separate regulations on electronic systems remains available, the issuance of regulations is not necessary as long as “all conditions of submission and receipt of data electronically are known and understood by the submitting parties.” *Id.* Policy statements and guidance documents can provide sufficient guidance to ensure secure electronic implementation of program requirements, while allowing greater adaptability to changing technology.

Under GPEA criteria, the vast majority of the FDA-regulated relationships currently subject to Part 11 are low-risk transactions. OMB has recognized that “transactions between a regulatory agency and a publicly traded corporation or other known entity regulated by that agency” generally carry “a relatively low risk of repudiation or fraud, particularly where the regulatory agency has an ongoing relationship with, and enforcement authority over, the entity.” OMB GPEA Procedures ¶ II.5.a. Rather than a relatively static, prescriptive regulation such as Part 11, therefore, GPEA calls for a flexible approach that allows industry to adopt appropriate technologies consistent with the overall risk level of the transaction and the agency’s stated terms and conditions.

As set forth below, implementation of GPEA -- in conjunction with applicable predicate rules -- will address the security, authenticity and integrity concerns that motivated issuance of Part 11.

b) *Part 11 Requirements Relating to Electronic Signatures Are Unnecessary In Light Of GPEA*

GPEA defines “electronic signature” as

- a method of signing an electronic message that --
- (A) identifies and authenticates a particular person as the source of the electronic message; and
- (B) indicates such person’s approval of the information contained in the electronic message.

GPEA § 1710(1). “[C]onsistent with other accepted legal definitions of signature,” this “flexible” definition is intended to permit “the use of different electronic signature technologies.” *See* OMB GPEA Procedures ¶ II.2.a.

Regardless of the technology used, however, GPEA requires that any electronic signature used by regulated parties in recordkeeping or submissions must “identif[y] and authenticate[]” the signer of the document, and must “indicate[] such person’s approval” of the information in the record. GPEA § 1710(1).

(1) Controls Relating to Uniqueness of Signature and “Link”  
Between Signature and Record (§§ 11.100(a), 11.70, 11.50)

Several Part 11 requirements specific to electronic signatures are simply redundant in light of GPEA. For example, Part 11 specifies that each electronic signature “shall be *unique* to one individual and shall not be reused by, or reassigned to, anyone else.” 21 C.F.R. § 11.100(a) (emphasis added). This regulation duplicates the GPEA requirement that electronic signatures in transactions with federal agencies must “identif[y] and authenticat[e] *a particular person* as the source of the electronic message.” GPEA § 1710(1)(A) (emphasis added).

Similarly, Part 11 requires that signatures executed to electronic records be “linked” to the record “to ensure that the signatures cannot be excised, copied, or otherwise transferred” -- *i.e.*, no “cut and paste” for electronic signatures. 21 C.F.R. § 11.70. Under the GPEA standards cited above, an electronic signature must be a mechanism that identifies a particular person as the signer of a particular record. This GPEA requirement could not be satisfied by a technology that allowed electronic signatures to be “cut and pasted” from one document to another.

The “signature manifestation” requirements of Part 11, *see id.* § 11.50, are also largely superseded by GPEA electronic signature requirements for parties doing business with federal agencies. “Signature manifestation” under Part 11 requires that each electronic signature be associated with the printed name of the signer, the date and time of execution, and the “meaning (such as review, approval, responsibility, or authorship)” associated with the signature, and that this information be available in any “human readable” form of the electronic record. *Id.* Under GPEA, an electronic signature must not only identify the signer, but must also “indicate[] such person’s approval of the information contained in the electronic message.” GPEA § 1710(1). Therefore, under GPEA as under Part 11, the “meaning” of the signature must be evident from the document to which the signature is appended. As for the Part 11 requirement that the signature bear the date and time, and that all elements of the “signature manifestation” be available in “human readable” form, manufacturers must already fulfill these requirements in order to comply with predicate rules. *See, e.g.*, 21 C.F.R. §§ 211.180, 211.182, 211.186, 211.188, 211.196, 820.80, 820.160, 820.184.

(2) Controls Relating to Non-Repudiation (§§ 11.10(j),  
11.100(b), (c))

Several Part 11 requirements are intended to prevent repudiation of electronic signatures. For example, Part 11 requires regulated entities to establish and adhere to “written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures.” 21 C.F.R. § 11.10(j). Part 11 also requires that regulated entities verify individual identities before assigning electronic signatures, and requires certification to FDA (on paper) that those signatures are “intended to be the legally binding equivalent of traditional handwritten signatures.” *See id.* § 11.100(b), (c).

Under GPEA criteria, however, most FDA transactions with regulated entities carry a low risk of repudiation. *See* Section 2(a)(2) above. GPEA requires federal agencies to ensure that the conditions placed on acceptance of electronic documents and signatures reflect

the level of risk associated with the transactions at issue. To the extent controls are necessary to guard against repudiation of electronic signatures in transactions currently subject to Part 11 -- transactions generally conducted in the context of ongoing relationships with entities over which FDA holds extensive regulatory and enforcement authority -- such controls can be effectively articulated as a set of “terms and conditions” in a policy or guidance document, as recommended by OMB. *See* OMB GPEA Procedures ¶ II.8.b. This approach would also enable FDA and regulated entities to better accommodate changes and improvements in electronic signature technology. *See id.* ¶ II.3.b(3).

(3) Controls Relating to Specific Electronic Signature Technologies (§§ 11.200, 11.300)

Finally, Part 11 includes detailed provisions intended to ensure that the proper controls are in place for specific types of electronic signature technologies. The regulations entitled “Electronic signature components and controls” impose special controls on “[e]lectronic signatures that are not based upon biometrics.” *See* 21 C.F.R. § 11.200(a). Specifically, individual signers using such “non-biometric” systems must use “at least two distinct identification components such as an identification code and password” each time a document is electronically signed, unless a series of signings are executed “during a single, continuous period of controlled system access,” in which case only one identification component is required. *Id.* § 11.200(a)(1). Part 11 further requires that non-biometric electronic signatures “[b]e used only by their genuine owners,” and be administered so that use of a signature by anyone other than its owner would require “collaboration of two or more individuals.” *Id.* § 11.200(a)(2), (3).<sup>9</sup>

As an initial matter, the applicability of these “non-biometric” system requirements is somewhat uncertain in light of the varied and changing technologies available for electronic signatures. As OMB noted in its GPEA implementing procedures, several technologies that are not entirely biometric may nonetheless contain biometric components. For example, a “smart card” -- a plastic card containing a chip that authenticates the user’s identity -- may be used in conjunction with a PIN, and the PIN may be based on a biometric. *See* OMB GPEA Procedures ¶ II.7.a(2). Likewise, a “digitized” signature is simply a “graphical image of a handwritten signature,” but may have a biometric component based on “duration, pen pressure, etc.” *Id.* ¶ II.7.a(3). While Part 11 does define “biometrics,” that definition does not account for technologies that have a biometric component.<sup>10</sup> It is questionable whether the security controls set forth in 21 C.F.R. § 11.200 are entirely necessary for all of the systems to which the regulation is potentially applicable. Under GPEA principles of compatibility with industry standards and adaptability to changing technologies, as well as the mandate that controls be

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<sup>9</sup> With regard to biometric systems, Part 11 simply indicates that these “shall be designed to ensure that they cannot be used by anyone other than their genuine owners.” *See* 21 C.F.R. § 11.200(b).

<sup>10</sup> Part 11 defines “biometrics” as “a method of verifying an individual’s identity based on measurement of the individual’s [unique and measurable] physical feature[s] or repeatable action[s].” *Id.* § 11.3(a)(3).

tailored to the level of risk associated with a given set of transactions, FDA’s terms and conditions for the acceptance of “non-biometric” signatures might be better articulated in policy documents.

Part 11 contains a separate regulation applicable to electronic signatures that are “based upon use of identification codes in combination with passwords.” 21 C.F.R. § 11.300. This regulation imposes controls such as regular password updates, periodic testing of identification devices, deauthorization of lost or stolen devices, and “immediate” reporting of unauthorized use. *Id.* § 11.300(a)-(e). As with the “non-biometric” regulations discussed above, this regulation reflects a static picture of available technologies that may not describe the varied and changing reality of electronic signature systems. A system “based upon” identification codes (including PINs), in combination with passwords, may or may not contain biometric elements or other features that affect the system’s security profile. For the reasons stated in the previous paragraph, therefore, FDA’s terms and conditions for the acceptance of identification code/password systems might be better articulated in policy documents than in a static regulation.

c) *Part 11 Controls For Electronic Record Systems Are Addressed By Implementation of GPEA And Predicate Rules*

All FDA-regulated entities subject to Part 11 are also subject to predicate regulation. Under GPEA, compliance with these predicate requirements cannot be limited to paper documents and conventional signatures. Rather, under GPEA, agencies must permit regulated parties to satisfy predicate requirements by using electronic documents and electronic signatures. *See* GPEA § 1707; OMB GPEA Procedures ¶ I.1.

The following sections discuss the Part 11 controls applicable to electronic systems, which are intended to ensure the “authenticity, integrity, and where appropriate, the confidentiality of electronic records.” *See* 21 C.F.R § 11.10.<sup>11</sup> These concerns remain critical to FDA’s protection of the public health. In light of GPEA, however, the electronic system controls set forth in Part 11 can be fully addressed by enforcement of the predicate regulations governing FDA-regulated industries.<sup>12</sup>

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<sup>11</sup> The controls in 21 C.F.R. § 11.10 apply to “closed systems.” “Open systems,” in which access is not controlled by the individuals responsible for creating the documents held on the system, are subject to all the controls listed in § 11.10, plus “additional measures such as document encryption and use of appropriate digital signature standards” as necessary to ensure “record authenticity, integrity, and confidentiality.” *Id.* § 11.30. GPEA and applicable predicate rules make no distinction between closed and open systems, and therefore that distinction is not retained in the analysis contained in this petition. If FDA concludes under the GPEA risk assessment that different controls are necessary for open as opposed to closed systems, that distinction can be reflected in a policy document. *See* Section 2(a)(2) above.

<sup>12</sup> As examples of predicate regulation, this petition references the good manufacturing practice (GMP) requirements of 21 C.F.R. Part 211, which apply to manufacturers of drugs (including animal drugs), and the quality systems regulation (QSR) requirements of 21 C.F.R. (continued...)

(1) Operational System Checks and Device Checks (§ 11.10(f) and (h))

One important concern reflected in the Part 11 regulations on electronic systems is the need to ensure the reliability of systems that generate and maintain electronic records and signatures. For example, Part 11 requires the use of “operational system checks to enforce permitted sequencing of steps and events.” 21 C.F.R. § 11.10(f). Under good manufacturing practice (GMP) and quality system regulation (QSR) requirements, however, regulated entities are already required to have documented procedures to control all aspects of the production and manufacturing process. *See id.* §§ 211.100(a), 820.70(a). Any deviation from these procedures must be documented. *Id.* §§ 211.100(b), 820.70(b). Applied to an electronic system, these regulations clearly require manufacturers to impose checks on the sequencing of steps and events in any electronic system that is part of the manufacturing process.

Another Part 11 control for system reliability is the use of “device (*e.g.*, terminal) checks to determine . . . the source of data input.” 21 C.F.R. § 11.10(h). Existing GMP regulations already require that “[i]nput to and output from the computer or related system of formulas or other records or data shall be checked for accuracy.” *Id.* § 211.68(b). Under QSR, manufacturers must “monitor[] and control” all “process parameters” relating to systems used in production, and to the extent the output of a system “cannot be fully verified by subsequent inspection,” must establish documented procedures to validate, monitor and control the process. *Id.* §§ 820.70(a)(2), 820.75. Under these provisions, a manufacturer would be required to verify the input source of data and/or operational instructions to any system involving electronic records.

(2) Authority Checks, Limiting System Access, and Other Controls Relating to Personnel (§ 11.10(d), (g), (i))

Part 11 also reflects the importance of controlling all aspects of human interaction with automated systems, to ensure the integrity of electronic documents and signatures. For example, Part 11 requires the use of “authority checks” to ensure that only “authorized individuals” can “use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.” 21 C.F.R. § 11.10(g). Part 11 also separately requires that regulated parties must limit “system access” to “authorized individuals.” *Id.* § 11.10(d).

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Part 820, which apply to the device industry. Other industries currently subject to Part 11, including food and dietary supplement manufacturers, are subject to different regulations with regard to good manufacturing practices. *See, e.g.*, 21 C.F.R. Parts 110, 111. Regardless of the nature of the predicate rules applicable to a particular industry, however, GPEA provides standards for the use of electronic records and signatures in satisfaction of whatever predicate requirements are applicable to that industry. Therefore, the analysis set forth in this petition is equally applicable to all industries currently subject to Part 11.

GMP regulations already require that manufacturers exercise “[a]ppropriate controls” over automated systems “to assure that changes in master production or control records or other records are instituted only by authorized personnel,” and that all personnel (including those authorized to create electronic documents) be trained to perform their specific functions in accordance with applicable GMP requirements (including “written procedures required by [the] regulations”). *See id.* §§ 211.68(b), 211.25(a). Under QSR, manufacturers must document “instructions, standard operating procedures (SOPs), and methods that define and control the manner of production,” including aspects of production that involve electronic records, and must monitor and control “process parameters” of automated systems “during production.” *Id.* § 820.70(a)(1)-(2). In addition, QSR requires management to establish the “authority” of “all personnel” who perform work “affecting [product] quality,” including work involving electronic records. *Id.* § 820.20(b)(1). These predicate requirements could not be satisfied without a documented system of authority checks and other access limitation mechanisms to ensure that any individual using an electronic system, signing electronic records, accessing input or output devices, altering records, or performing other operations was properly authorized to do so.

Part 11 also requires that “persons who develop, maintain, or use electronic record/electronic signature systems” have the proper “education, training, and experience to perform their assigned tasks.” *Id.* § 11.10(i). Existing GMP and QSR regulations have very similar requirements. *See id.* §§ 211.25(a), 820.20(b)(2).

### (3) Control of System Documentation, Including Change Controls (§ 11.10(k))

Under Part 11, documentation of system operation and maintenance must be subject to controls on distribution, access, and use. 21 C.F.R. § 11.10(k)(1). Any modifications to system documentation must be tracked through revision and change control procedures. *Id.* § 11.10(k)(2).

Under GMP, manufacturers are already required to document any electronic systems, and to maintain that documentation in a secure fashion so that it is available for FDA review. *Id.* §§ 211.68(a), 211.180. In addition, manufacturers must exercise “[a]ppropriate controls” over that documentation, for example to ensure that changes are initiated only by authorized personnel. *Id.* § 211.68(b). “Appropriate controls” must include documentation of modifications to the system -- otherwise, it would be impossible to comply with the GMP requirement that modifications be initiated only by authorized personnel. QSR also requires documentation of systems, *id.* § 820.70(a)(1), documentation of any “production [or] process changes” affecting the system, *id.* § 820.70(b), and retention of systems documentation records, *id.* § 820.180(b). The need for documentation in revision and change control has been set forth in greater detail in FDA guidance. *See FDA Guidance, General Principles of Software Validation* (January 11, 2002) ¶ 5.2.7 (discussing different categories of system modifications including corrective, perfective and adaptive maintenance). These GMP and QSR requirements could not be satisfied without the maintenance and control of full systems documentation, including change control procedures to document modifications.

(4) Other Part 11 Controls: Validation, Audit Trails, Record Retention, Record Copying, and Legacy Systems

With regard to the five remaining categories of Part 11 controls not discussed above, FDA has indicated in guidance its intention to exercise enforcement discretion. As described below, in each of these areas -- validation, audit trails, record retention, record copying and inspection, and legacy systems -- FDA has directed industry to base its internal controls on a “risk assessment” and/or compliance with predicate regulations, in some cases supplemented with FDA policy or guidance documents. FDA’s approach to these remaining aspects of Part 11 is therefore very similar to the approach required for GPEA compliance, as discussed in Section 2(a)(2) above.

The Part 11 “validation” requirements for electronic systems are intended to ensure “accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.” 21 C.F.R. § 11.10(a). FDA has recognized in its recent guidance that these validation requirements are largely addressed in existing predicate rules. *See* FDA Part 11 Guidance ¶ III.C.1. Therefore, regulated parties have been instructed to base their validation procedures for electronic systems on these predicate rules and on “a justified and documented risk assessment.” *See id.* FDA has also referred industry to existing guidance on systems validation. *See id.* (citing FDA Guidance, *General Principles of Software Validation* (January 11, 2002); ISPE/GAMP Forum, *The Good Automated Manufacturing Practice Guide For Validation of Automated Systems* (2001) (GAMP 4)).

With regard to Part 11 requirements for audit trails, *see* 21 C.F.R. § 11.10(e), (k)(2), FDA has noted that certain predicate regulations contain similar requirements, and has indicated that regardless of predicate rule requirements, audit trails may be important to ensure “trustworthiness and reliability” of electronic records. *See* FDA Part 11 Guidance ¶ III.C.2. Regulated entities are instructed to base their internal audit trail requirements on “the need to comply with predicate rule requirements, a justified and documented risk assessment, and a determination of the potential effect on product quality and safety and record integrity.” *See id.*

With regard to Part 11 requirements on record retention, *see* 21 C.F.R. § 11.10(c), FDA has noted the applicable predicate rule requirements for record retention and availability. *See* FDA Part 11 Guidance ¶ III.C.5. FDA has further indicated that record retention policies should be based on “predicate rule requirements,” “a justified and documented risk assessment,” and “a determination of the value of the records over time.” *Id.*

Part 11 requirements on record copying, *see* 21 C.F.R. § 11.10(b), will be subject to enforcement discretion provided FDA investigators are given “reasonable and useful access to records” and predicate rules on record inspection are complied with. *See* FDA Part 11 Guidance ¶ III.C.4 (recommending that copies preserve “the content and meaning of the record” and be made available “in a human readable form”).

Finally, FDA will exercise enforcement discretion in applying Part 11 to legacy systems (*i.e.* those systems operational prior to August 20, 1997), provided the system met all applicable predicate rule requirements before August 1997 and currently complies with predicate

rules, and provided the manufacturer has documented the fitness of the system for its intended use. *See id.* ¶ III.C.3.

3. In Light of the Subsequent Enactment of GPEA, Part 11 Should Be Revoked

When FDA was preparing its proposed rule on Part 11, the agency received a comment suggesting that no new regulations were needed to implement the use of electronic documents and signatures. Instead of issuing new regulations, the comment suggested that FDA should issue a “policy statement or inspectional guideline” that would “broadly accept electronic identification/signatures” and “establish criteria for the degree of security required.” *See* 59 Fed. Reg. 45,160, 45,165 (proposed rule notice). In issuing the proposed rule, FDA responded that “a policy statement, inspectional guide, or other guideline would be an inappropriate vehicle for accepting electronic signatures because such documents do not have the same legal significance as substantive regulations that require signatures [*i.e.*, predicate regulations].” *Id.*

This response reflected FDA’s view, prior to issuance of Part 11, that a separate rulemaking process was required to ensure electronic records and signatures could be accepted in satisfaction of agency regulations. At the time Part 11 was proposed, FDA’s position was that predicate rules did not permit the use of electronic records and signatures. *See id.* (“The agency does not agree with the assertions that . . . the CGMP regulations currently permit alternatives to handwritten signatures or initials.”).

The basis for FDA’s analysis was fundamentally changed by the enactment of GPEA one year after Part 11 was issued. Under GPEA, federal agencies are required (as of October 2003) to accept electronic records and signatures in satisfaction of any agency regulation requiring the maintenance or submission of information. *See* GPEA § 1707. As discussed in this petition, GPEA calls for the acceptance of electronic records and signatures through the implementation of existing predicate rules, supplemented to the extent necessary by policy statements that ensure system security without inhibiting technological innovation. Part 11, by contrast, is a static and prescriptive regulation that is difficult to adapt to developing technologies.

The Part 11 provisions on both electronic signatures and electronic system controls are superseded by GPEA. No specific statutory mandate required the issuance of Part 11, and the Part 11 regulations no longer serve any independent public health purpose. Rather than attempting to rework this unwieldy regulation through the issuance of guidance documents, FDA should revoke Part 11 in its entirety and pursue implementation of electronic document and signature technologies under GPEA standards in conjunction with applicable predicate rules.

C. *Environmental Impact*

This petition is categorically exempt from the requirement for an environmental assessment or an environmental impact statement pursuant to 21 C.F.R. § 25.30.

*D. Economic Impact*

Information on the economic impact of the petition will be provided upon request.

*E. Certification*

The undersigned certifies that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner that are unfavorable to the petition.

Respectfully submitted,



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Appendix A

Industry Coalition on 21 CFR Part 11

Advanced Medical Technology Association

America's Blood Centers

Animal Health Institute

Consumer Healthcare Products Association

Cosmetic, Toiletry, and Fragrance Association

Council for Responsible Nutrition

Council on Radionuclides and Radiopharmaceuticals

Generic Pharmaceutical Association

Medical Device Manufacturers Association

National Electrical Manufacturers Association

National Food Processors Association

National Grain and Feed Association

Pharmaceutical Research and Manufacturers of America