Memo of Meeting

Date: February 20, 2001

Location: Rockville, MD

Subject: Implementation of 21 Code of Federal Regulations, Part 11; Electronic Records; Electronic Signatures

Representing the Industry Coalition on 21 CFR Part 11:

Mr. William Bradley, VP, Technical Affairs, Consumer Health Care Products Association

Mr. Christopher Allen, VP. Operations, Northern Americas Region, Bayer Corporation

Ms. Sia Economides, Senior Scientist, National Food Processors Association

Mr. Bernie Liebler, Director, Technology & Regulatory Affairs, Advanced Medical Technology Association

Mr. Dave Everson, IT Management Solutions, Inc.

Mr. Donald A. Cadge, Director of Contract Operations and New Business, McNeil Consumer Healthcare

Mr. Alan Goldhammer, Associate Vice President U.S. Regulatory Affairs, Pharmaceutical Research and Manufacturers of America

Mr. Evjar Conen, QA Information Tech. Specialist, Generic Pharmaceutical Association

Mr. Robert Rhouer, Director, Validation Security, Animal Health Institute

Ms. Vicki Schofield, Industry Manager, National Electrical Manufacturers Association

Mr. Ron Menger, VP, Engineering, McNeil CPC (Consumer Health Care Products Association)

Mr. Robert Steinmeir, 21 CFR Part 11 Program Director, Abbot Labs.

Mr. Donald Ellis, Dir. Reg. Affairs, Kodak

Mr. Will Robinson, Staff VP, CR Bard, Inc.

Mr. Johnny Long, Director, Quality Mgm't, Baxter Healthcare Corp.

Mr. Robert Kanaley, Quality Systems Div. Guidant Corp.

Mr. Sandy Phelan, Dir, Reg Affairs, Animal Health Institute

Mr. Glen Thomson, Compliance Assurance Services, Bristol Myers Squibb

Representing the Food and Drug Administration, FDA Part 11 Compliance Committee:

Mr. John Taylor, Director, Office of Enforcement

Mr. Paul J. Motise, Consumer Safety Officer, Office of Enforcement

Dr. James McCormack, Consumer Safety Officer, Office of Enforcement

Dr. Randy Levin, Medical Officer, Center for Drug Evaluation and Research

Ms. Sonal Vaid, General Attorney, Office of Chief Counsel

Mr. Tom Chin, Consumer Safety Officer, Office of Enforcement

Mr. Mark Hackman, Consumer Safety Officer, Center for Food Safety and Applied Nutrition

Mr. Stewart Crumpler, Regulatory Officer, Center for Devices and Radiological Health

Mr. John F. Murray, Software Engineer, Center for Devices and Radiological Health

Dr. Vernon Toelle, Math Statistician, Center for Veterinary Medicine

Mr. Charles Ahn, Consumer Safety Officer, Office of Regional Operations

Ms. Jennifer Thomas, Associate Director for Policy, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research

The meeting was requested by the industry coalition to discuss implementation of 21 CFR Part 11. This meeting was a follow up to the one we had with the group in September of 2000. (John Taylor and Randy Levin were present for only a portion of the meeting.)

After introductions we discussed the following.

Coalition's work:

Since our last meeting the coalition added two additional medical device industry trade groups and formed eight project teams to prepare comments for submission to FDA's dockets.

FDA Part 11 guidance documents:

We informed the coalition members that we were preparing guidance documents on validation, time stamps, electronic copies for FDA, archiving, a glossary and audit trails, with scope being covered on a separate track. We said that we could not predict when the guidance documents would be published, but that the ones on validation and the glossary would likely publish first. All are level 1 guidances that would be published in draft for public comment.

The coalition expressed concern that their views would not be taken into account unless they submitted their comments into the established dockets before the draft guidances were published. We clarified that comments from all interested parties would be considered before final guidance is published, in accordance with FDA's Good Guidance Practices. Mr. Taylor encouraged the coalition to submit comments throughout the process, including prior to the issuance of guidance documents.

Implementation and scope of part 11:

Mr. Taylor explained that the rule has been in effect since 1997 and that FDA will publish is views to clarify the scope of the rule and the public would be able to comment on such document. He added that this will help FDA enforce the rule and will help industry understand agency expectations. He commented that some in industry thought the rule only applied to pharmaceuticals, but that, in fact, part 11 applies to all program areas.

FDA training activities:

Mr. Taylor summarized the measures we took to train the field in implementing part 11. These included: distributing the final rule Federal Register notice, distributing a distillation of the final rule preamble in the form of an "answers to frequently asked questions" document, airing a telecast to field districts, providing contract training courses, Intranet postings, on-site training, coverage in product specific courses, and day to day headquarters to field communications.

We discussed uniformity of training content and implementation of the rule and explained that, like other regulations, a number of activities work together to ensure as consistent an application of the rule as possible. These include training, common reference documents, routine lines of communication, and the checks and balances attendant to clearing regulatory actions. We added that any policy changes and information that is contained in the agency's final guidance documents will be conveyed to field units as part of future training.

Mr. Liebler said his group had engaged EduQuest to hear what training FDA investigators were receiving. He commented that EduQuest's Mr. Martin Browning had said that part 11 did not distinguish "documents" from "records." Mr. Motise stated that the preamble to the final rule explained that for purposes of part 11 there were no distinctions between the two, in that ,to the extent that information required by FDA regulation or law is recorded in some manner, the memorialization is considered a record.

In response to coalition questions, we commented that training materials would generally be releasable under the Freedom of Information Act. We also emphasized the fact that we are aware of the need to update earlier training to reflect any changes in the agency's policy. We said we also understand that future training will need to reflect the nuances of applying part 11 to specific FDA programs.

Enforcement:

Mr. Taylor explained that our part 11 enforcement policy, as reflected in the latest compliance policy guide, was still in place and that regulatory actions regarding part 11 needed concurrence of both the applicable center and the Office of Enforcement.

Mainstream activities:

We commented that our part 11 implementation is being influenced, and is essentially consistent with, mainstream regulatory standards of electronic commerce and electronic government. We explained that since our last meeting, for example, the Department of Justice and the National Archives and Records Administration had issued final guidance to federal agencies on implementing the Government Paperwork Elimination Act. We also noted the influence of the Electronic Signatures in Global and National Commerce Act and implementing regulations for the Health Insurance Portability and Accountability Act.

Food industry presentation:

Ms. Sia Economides gave a brief presentation to outline the challenges faced by her industry. She said that electronic controls and automation helped to promote more consistent and higher quality products because of reduced human interaction with the manufacturing process. She noted that information technology investments were a small part of the industry's budget and so these investments needed to be carefully allocated in light of regulatory requirements. She explained how it is sometimes difficult to ensure that different parts of a computer system worked properly together. She also relayed questions about what a record is in an environment of both paper and electronic elements. Ms. Economides asserted that because FDA had accepted paper printouts for many years, it should continue to do so. (Her presentation is attached.)

Ms. Economides said her organization is in the process of revising Technical Bulletin 43L which covers Automated Thermal Processing Systems.

During the ensuing discussions Ms. Economidies asked that part 11 implementation be linked with equipment life cycle replacements and upgrades and that a risk benefit approach be used for implementation of electronic records. We explained that we could not continue to accept past practices because experience has reinforced the need for part 11 controls. We said the rule helps ensure product quality, data integrity, but also addresses FDA's ability to effectively audit records and detect and deter records falsification. We illustrated the affect that inadequate electronic recordkeeping can have on product quality by noting a case in which a food processor whose inadequately validated electronic recordkeeping system caused distribution of misbranded foods that (some ingredients having been omitted from the labeling) were subsequently recalled.

In the post-presentation discussion, we explained that some records covered by part 11 were clearly more important than others, and that firms should take that into account in prioritizing their remediation efforts. However, we added that all of those records became requirements as a matter of notice and comment rulemaking or legislation, and so were all requirements of federal law.

We discussed the possibility of coalition members sharing information on vendor products and services so as to facilitate compliance with part 11 technical provisions. The coalition members stressed that as a trade association they could not engage in such activities because of restrain of trade considerations.

The meeting concluded after about two hours.

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HFC-300
FDA Meeting Attendees

The Food Industry Challenges in Implementing 21CFR Part 11

presented by Sia Economides, NFPA

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Value of Technology

- Definite value to use of electronic controls & systems
  - Greater control, less opportunity for human error
  - Product quality is more consistent
  - Promote and protect public health
- Recognize the intent of the regulation to create criteria for electronic recordkeeping technologies

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Today's Focus

Food Industry Challenges

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Food Industry Challenges

The most frequently asked question,

When is an E-record an E-record?

Because the answer has a significant investment impact

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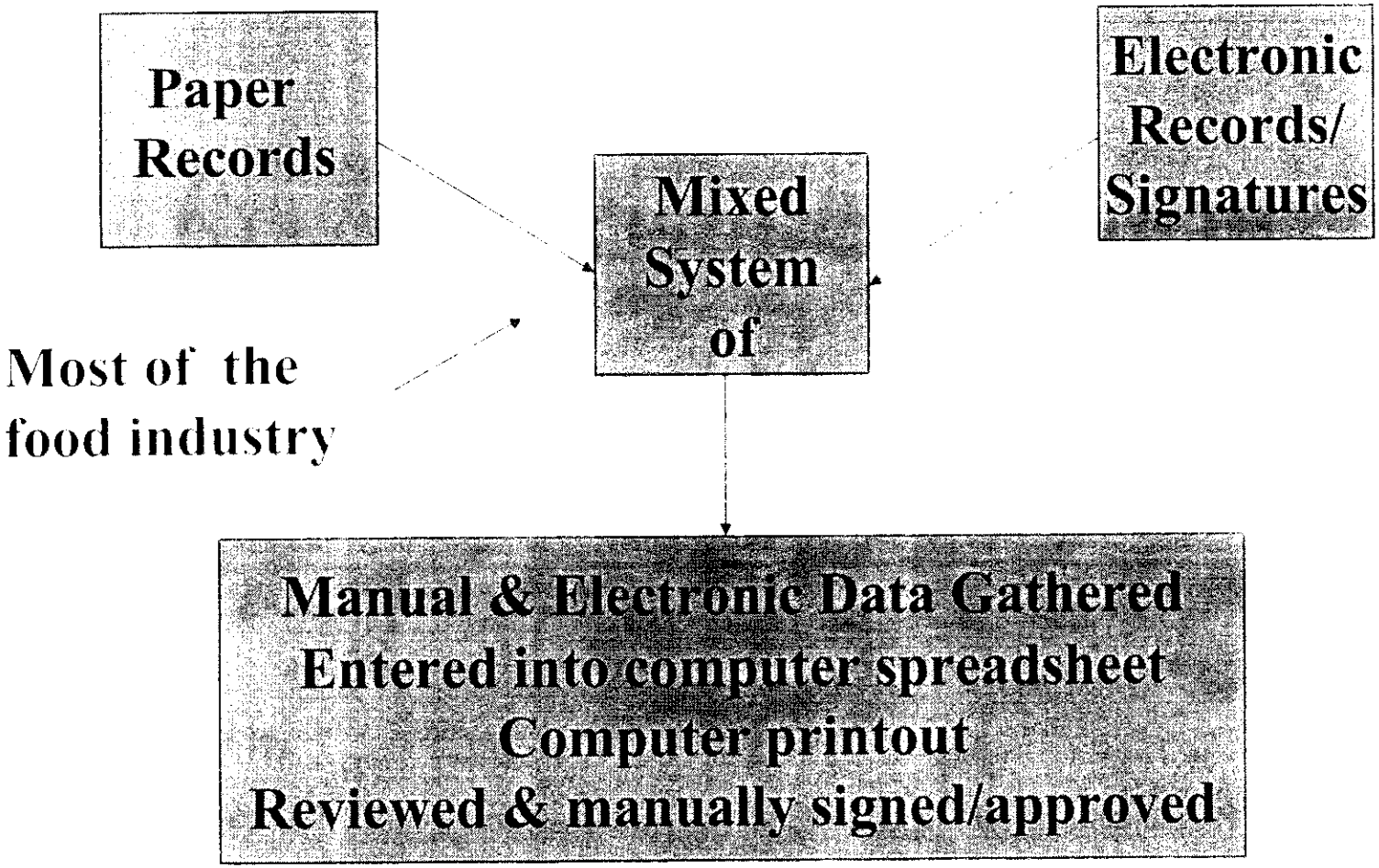
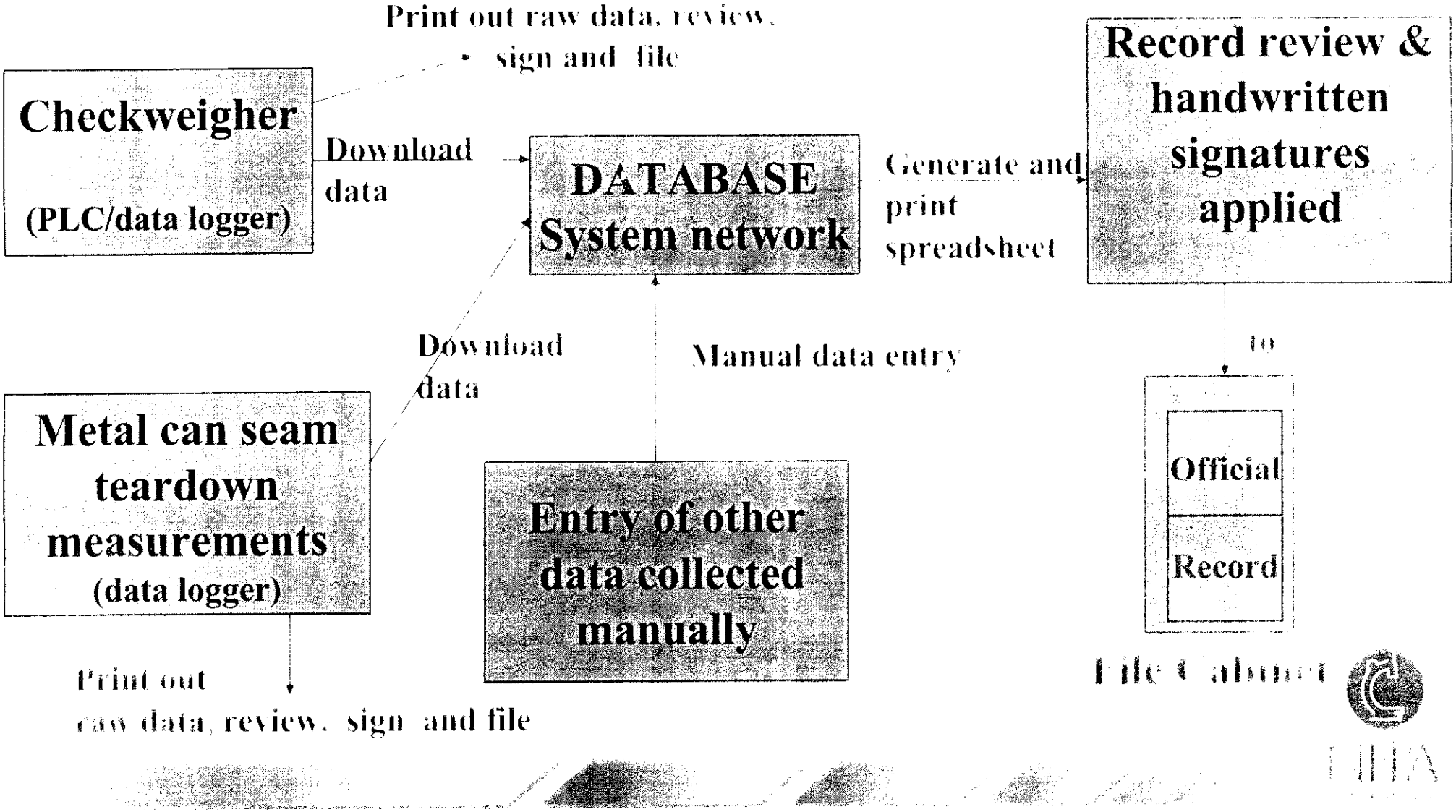
Record Keeping Scenarios



Typical Food Processing System



Food Industry Challenges

- Implementation timing
  - IT systems
    - Have become the backbone of factory operations but,
      - Factory/Corporate infrastructure not fully established
      - Software technology not fully developed
  - Computer integration and automation of operations are a priority
  - IT investment plans are by priority and within equipment replacement cycle
    - Capital required is large (cost benefit analysis tbd)

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Food Industry Challenges

- Compliance uncertainty due to diversity of interpretation is leading to:

  Deferral of IT investment

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Food Industry Challenges

- Validation & Verification Systems
  - Current practices include,
    - Microbiological Challenges
    - Allergen Testing
    - Corporate GMP's
    - NFPA , FDA and Industry proactive in revising guidelines for control systems used on aseptic processing and packaging systems

    Q: What is the cost benefit if these practices are acceptable and no additional value gained?
  - The limited availability of 3rd Party IT software compliance

    Q: Is software available to fit our current company infrastructures?

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Guidance Considerations

- Current systems are adequate to produce safe and quality food products.
- As with paper records, the point at which an electronic signature is applied would define the creation of an e-record subject to the requirements of an audit trail.
- The use of computer printouts as "raw data" should still be allowed because they have long been an industry standard and acceptable to FDA.

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Guidance Considerations

- Implementation should be part of the normal life-cycle of replacement and upgrades of equipment and systems.
- A risk/benefits approach should be applied to guide the implementation.
- An economic impact analysis should be conducted to guide the implementation

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