PMFNewsletter

A quarterly publication of the Pharmaceutical Microbiology Forum

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President's Message

The organizational board of PMF, along with our members will have our 6th annual meeting in Wilmington, N. C. on Tuesday, April 15, 1997. As we prepare for the upcoming events, we ponder on the changes that have been proposed and revised over the past years, and find that major changes will soon be implemented in USP Preservative and Sterility Testing. Requirements to perform microbial assessments in all raw materials and non-sterile finished dosage forms are expected to become official in the near future.

A few new products in the market have made our laboratory lives easier. Two that come to mind are Bacterial Endotoxin Challenge vials and vials with predetermined microbial populations. The first of these products offered by most of the endotoxin vendors facilitate depyrogenation validations, as long as one does not desire more than a 3 log reduction. The vials come with 1000 endotoxin units (EU) each. The second product, the vials with predetermined microbial populations have helped people target microbial populations specified in growth promotion studies. This product has also assisted microbiologists in achieving the high populations required for antimicrobial preservative effectiveness testing. In this age of rapid technological advances, we expect to continue simplifying life in the microbiology laboratory.

We hope to see you at PMF's Annual Meeting.

Laura

Come Visit Our Website at
http://www.microbiol.org/PMF.htm
We also welcome you to visit the Microbiology BBS site at http://www.microbiol.org

MICROTOONS

We are in need of new microtoons to fill this space. Please send your original microtoons to the attention of PMF, c/o Laura Valdes-Mora.

IN THIS ISSUE:

The following summaries are from presentations given at the AAI seminar series- Microbiology Requirements and Regulatory Compliance in the Pharmaceutical Industry, held in Wilmington, NC April 22-23, 1996.

Regulatory Compliance Issues in the Microbiology Laboratory

This presentation focused on what Standard Operating Procedures (SOP's) should be in place and what should be covered under each one.

Receipt of Media should have documentation (SOP) that defines:

1) Date Received
2) Date Opened
3) Labelling instructions
4) Approved vendors
5) Assignment of expiration date
6) Testing growth promotion requirements
7) Storage specifications

Media Preparation documentation requires the recipe to be in writing, i.e. Batch Record, which defines

1) Lot numbering
2) Expiration Date
3) pH specifications
4) List inactivators (if needed)
5) Sterilization parameters

Media sterilization documentation should include:

1) Load configurations (container size, number and orientation)
2) Cycle parameters (time, temperature, pressure, drying time, if necessary).
3) Quality Assurance Review criteria

Prepared media documentation should include:

1) Growth promotion and sterility testing of medium defines:

a) Storage requirements and age of challenge organisms

b) Challenge parameters

1. frequency
2. volumes of challenge organisms
3. type of challenge organisms
4. preparation of inoculum

c) incubation parameters (time, temperature, etc.)
d) controls (negative and medium)
e) enumeration procedures
f) acceptance criteria

3) Quarantine requirements until growth promotion and sterility have been determined

4) Holding method for molten agar

5) Description for handling containers, i.e. securing screw caps after sterilization

6) Visual inspections

7) Pre-incubation of purchased medium

Quality Control Documentation should include:

1) Receipt of purchased medium

2) Preparation records

3) Sterilization records

4) Growth promotion record

5) Review process

Quality Assurance records should also include:

1) Validation of equipment defines:
a) frequency of re-validations
b) protocol for validation
c) acceptance criteria

2) Calibration of equipment defines:
a) method of calibration
b) frequency of calibration
c) acceptance criteria

3) Preventative maintenance of equipment

4) Validation of test methods

5) Training of personnel defines:
a) when and how training is to be performed
b) who is responsible for training
c) documentation that it is in place for protocol execution
d) review or retraing procedures

Review procedures define:
investigation of failures
release of medium for use
(cont. pg. 4)

International Harmonization of the Sterility and Antimicrobial Effectiveness Tests

Sterility
It is recommended that when using membrane filtration technique, the whole contents of the container be filtered, but not less than the quantities indicated in the USP table.

The total volume washed through one single filter must not exceed 1000 mL, unless otherwise justified and authorized.

Some filter manufacturers indicate that after a membrane is presented with more than 1000 mL of any liquid, microorganisms can be washed through the filter.

Antimicrobial Effectiveness Testing
No increase is defined as not more than 0.5 $\log_{10}$ unit higher than the last value obtained.

Products are divided into 4 categories. Each category has different pass/fail (acceptance) criteria.

Product Categories

Category	Product Description
1	Injections, other parenterals, including emulsions, otic, sterile nasal products made with aqueous bases or vehicles.
2	Topically used products made with aqueous bases or vehicles, non-sterile nasal products, and emulsions, including those applied to mucous membranes.
3	Oral products, (other than antacids) made with aqueous bases or vehicles.
4	Antacids made with aqueous bases or vehicles

Sampling Intervals

	Days			
Products	7	14	21	28
Category 1	X	X	X	X
Category 2	--	X	X	X
Category 3	--	X	X	X
Category 4	--	X	X	X

Acceptance Criteria

For Category 1 Products	
Bacteria	Not less than 1.0 log reduction from the initial calculated count at 7 days, not less than 3.0 log reduction from the initial count at 14 days, and no increase from the 14 days count at 21 and 28 days.
Yeast and Molds	No increase from the initial calculated count at 7, 14, 21 and 28 days.
For Category 2 Products	
Bacteria	Not less than 2.0 log reduction from the initial calculated count at 14 days, and no increase from the 14 days count at 21 and 28 days.
Yeast and Molds	No increase from the initial calculated count at 14, 21 and 28 days.
For Category 3 Products	
Bacteria	Not less than 1.0 log reduction from the initial calculated count at 14 days, and no increase from the 14 days count at 21 and 28 days.
Yeast and Molds	No increase from the initial calculated count at 14, 21 and 28 days.
For Category 4 Products	
Bacteria	No increase from the initial calculated count at 14, 21 and 28 days for *S. aureus* and *E. coli*.
Yeast and Molds	No increase from the initial calculated count at 14, 21 and 28 days.

Interpharm Harmonization Meeting of the EP, JP and USP, February 5-6, 1996, Barcelona, Spain

Preservative Effectiveness Testing

Test organisms:

- Inclusion of E. coli to harmonize Pharm. Eur. To USP and JP.
- Additional national culture collection numbers will be included, if they are closely related.
- Environmental isolates are not recommended.

Inoculum:

- Cultivation on solid agar will be recommended (not liquid).
- Inocula will be "freshly" prepared (store NMT 1 hr. or 1 day).
- Inoculum should be as low a volume as possible (0.5-1.0%).
- Cell Numbers should be expressed as cfu/mL.

Test Samples:

- Storage of product in final container is required, test out of the original container for technical reasons is permitted.

(cont. pg.. 4)

(Interpharm Harmonization, cont.)

Questions to be Resolved:

- Alternative media for fungi (JP to respond

- Non-aqueous preparations - rationale and test method to be supplied by USP.

- Validation methods
  a) Recovery of microorganisms
  b) t_0 time point
  c) Validation of microbial resistance

Scope of the Sterility Test and Parametric Release

Manufacturing Process

- A clear distinction was seen between product manufactured using terminal sterilization and those aseptically processed - the sterility test may have different impact on the two types of products.

Referee Test

- Full agreement that the sterility test is a referee test in case of doubt or dispute.

- Willingness on the part of Japan to accept results from a harmonized sterility test.

- RETESTING only allowed if the test was invalid - this requires good evidence that the product was not at fault.

Validation and Requalification

- Not necessary to revalidate each time the lot of media changes, but periodic revalidation is necessary.

Parametric Release

- Guidance needed on validation and on criteria for parametric release.

Sterility Test Methodology

Duration:

- 14 day agreed by EP, JP, USP.

Culture Media:

- Composition of media not agreed to - is composition mandatory or not. This point remains unresolved.

Sterility test of media may be done I parallel with test, but must be carried out to the full 14 days.

- Storage of media will be at 2-25°C; no requirement for storage in the dark.

- Growth promotion test will have:
  a) Inoculum of 10-100 cfu/mL
  b) Growth within 3 days for bacteria & yeast
  c) Growth after 5-7 days for mold
  d) Delete copious in Ph.Eur.
  e) Change tube to container

Bacteriostasis/Fungistasis

- Validation of test - only done after conditions of test change.

- Title should change to recovery of micoorgansisms

Product Turbidity

- Transfer to secondary medium after 14 days , then incubate at least another 7 days.

Sterility Test Criteria

Sampling Techniques:

- A table describing minimum volume per sample is needed

- Some problems with current sampling of small volumes requires work (0.1 mL single dose requires 50 units for 5 mL minimum).

Minimum Number of Units:

- Clear preference for 20 samples/batch, rather than 40 samples/batch.

Sampling Plan:

- A clear plan must exist when this is used as a release test. The sampling must be representative of run. Guidance will be placed in a non-mandatory section.

Retesting:

- Clarification of current Pharm. Eur. text required to confirm that a retest is *unrelated to the product.*

Overall, the conference is highly optimistic of probability of world-wide harmonization of sterility test.

There will be an informational chapter in the USP covering validation of Microbial Recovery from pharmaceutical products.

Media Quality Control requires:

1) Record traceability for preparation, sterilization and growth promotion.

2) Negative controls at item of use.

3) Back challenge negative growth test dates.

4) Visual inspection.

Organism Receipt Procedure

1) Define culture source.

2) Define purity/authenticity.

(cont. pg. 5)

(Regulatory Compliance, cont.)

3) Verify species.

4) Conduct visual inspection.

Organism Revival and Maintenance

1) Define hydrating fluid and volumes.

2) Define revival medium and type.

3) Define incubation duration and temperature.

4) Describe storage technique.

5) Determine transfer frequency and number(use the seed lot technique.

6) Define maintenance medium and incubation.

7) Describe documentation requirements.

Inoculum Preparation Procedure

1) Describe storage, revival and enrichment process.

2) Define harvesting technique.

3) Describe dilution and enumeration technique, to include suspending solution medium and incubation parameters.

4) Describe storage conditions.

Biological Waste Procedures

1) Describe containment.

2) Have a spill plan.

3) Describe disposal method(s)

Organism Quality Control Procedures

1) Include receipt verification.

2) Define controls for aseptic handling.

3) Define storage temperature and duration.

4) Perform periodic identification and purity assessments.

5) Describe plate count accuracy and reproducibility.

6) Organism Raw Data

7) Describe receipt records.

8) Keep and describe a transfer maintenance log book or system.

9) Define how to prepare inocula and how organisms will be enumerated.

10) Describe what would be considered Quality Control results.

Organism Maintenance Training

This topic should cover:

1) Aseptic techniques.

2) Speciation (microbial identification) methods.

3) Long-term storage.

4) Record keeping requirements.

5) Describe review and acceptance process.

Equipment/Facility Validation Procedure

1) Validation Master Plans should describe equipment validation frequency and assign responsibility for testing, review, etc.

2) Should describe how protocols are to be written (contents) and approvals required. Acceptance criteria should be established up front.

3) Revalidation requirements are to be established.

4) The company's change control process should be described. It should establish the personnel to be involved, what items will be reviewed, and what the approval and documentation practices are.

Highlights of the PDA 1996 Annual Meeting

The PDA annual meeting was held in Philadelphia from November 18-20, 1996. It was the 50th Anniversary of the PDA, which has now become an international organization. Highlights of the seminars follow:

A Survey of Industry Practice in the Visual Inspection of Injectable Products: John Shabushnig, Ph.D., Pharmacia and Upjohn, Inc.

27% of 75 companies responded to the survey

- Typical rejection rated at 0.1 to 5% with 1.9% the mean for solutions.

- Typical rejection rates are 0.1 to 2.5% with a 1% average for lyophilized products.

(cont pg. 6)

(PDA Highlights cont.)

- The most common defects in the following order are: 1) particulates, 2) crimps, 3) cracks, 4) scratches, 5) fill defects, 6) lyophilized cake appearance, 7) leaks, 8) plugs, and 9) caps.

- The most common particulate identified in sequential order are: 1)lint/fibers, 2) glass, 3) product related, 4) metal, and 5) rubber.

Audit Techniques for Bulk Pharmaceutical Chemicals: John Lee, Pharmaceutical Compliance Associates

- The typical GMP walkthrough is not appropriate for the bulk chemical plant. There are few people and most of the production occurs within piping, so you cannot see anything.

- The first question he asks is whether there are any penicillins or cephalosporins produced here. If so, he leaves and ends the audit.

- On the Internet, FDA has issued a proposed guideline for discussion. It is available from : http:///www.fda.gov/cder/guidelines. It is entitled *Manufacture, Processing or Holding of Active Pharmaceutical Ingredients.* Also, there is the 1991 FDA *Inspection Guide for BPCs.*

USP Update: Joseph Valentino, USP

- They are working on a chapter for gene/cell therapy, but no progress thus far.

- Also, no progress being made on standards for selected biomaterials.
- The elimination of 'pyrogen-free' from labels is under consideration.

- USP has provided the WHO with an endotoxin standard for harmonization. Jim Cooper, President of Endosafe, has a letter from WHO accepting this standard, which formally states that 1 IU = 1 EU, so harmonization is official.

- The 3rd revision of the General Chapter <1116> Microbial Evaluation of Clean Zones will be out in January/February 1997 edition of the *PF.*

Focus Group on Sterility Testing

- A lunchtime focus group was sponsored by EPP, who is a manufacturer of a proposed new sterility testing monitoring device. This device uses transducers to measure changes in gas pressure produced by contaminants (if present) in a sterility test. The concept is one that would be able to determine the presence of contamination much sooner than by the present visual approach (thus reducing the length of incubation) and would be particularly helpful to folks whose test products are turbid (such as blood products). EPP was seeking comments as to the marketability of such a product. Most folks were concerned about the price (>$50,000) and whether USP/EP or FDA would consider this an acceptable alternative to the current sterility test.

Opening Remarks: Ed Fry, President, PDA

- PDA Technical Report No. 22 on Aseptic Processing will be published around January.

- PDA Technical Report No. 23 Industry Survey on Current Sterile Filtration Practices chaired by Jim Wilson and Theodore Meltzer will be published soon.

- Also, coming soon are the survey results on aseptic processing practices.

- PDA is also becoming increasingly involved in CMC (Chemistry and Manufacturing Controls) revision.

- The PDA Training Institute at the University of Baltimore will be ready in the Spring of 1997. There will be laboratory based hands-on training courses there.

A Pragmatic Approach to Cleaning Validation: John Voss, Kemper-Masterson, Inc.

There are 5 steps to "How to Validate Cleaning":

- Develop a cleaning plan.

- Qualify the cleaning system itself (IQ-is it installed correctly; OQ - Does it operate correctly?).

- Perform cycle development.

- Test cycle with product.

- Perform PQ (3 runs).

Acceptance criteria may be based on the following:

- Based on scientific rationale.

- Should be practical.

(cont pg. 7)

- Use for information only (FIO) as needed to build a statistical database.
- LD_{50} - toxic dose criteria may not be practical for biologics.
- Final rinse water should meet incoming water quality limits.
- FIO for TOC to develop SPC upper/lower control.
- For multiple product facilities, may use 1/1000 of therapeutic dose of Product A carried over into Product B.
- Mullen , and Fourman method may be used.

The PDA has published a text on cleaning validation of which John was the committee chairperson.

Statistical Analysis of Environmental Monitoring Data: Does a Worst Case Time for Monitoring Clean Rooms Exist?: Anthony Cundell, Wyeth-Ayerst Labs and Wyeth-Lederle Vaccines

- His group did a retrospective study of 1994 data to determine whether there was a particular time of day which would be the ideal time to monitor (i. e. when alert or action levels would be exceeded most frequently). There were 1256 monitoring occasions with 17,935 sites monitored. The outcome was that there was no worst case time for environmental sampling.

Microbial Control and Isolation Technology: James Agalloco, Agalloco and Associates

Jim raised the following ideas on the use of isolator systems:

- Perform media growth promotion using 1-10 cfu rather than the current 10-100, since the peroxide sterilant may inhibit the media and you want to be able to show that you can recover low levels of organisms.
- You should expect the contamination in the isolator to be at zero, since you sterilized the entire interior of the unit. Therefore, one should not set action limits higher than zero.
- Active air samplers such as RCS or STA have too short sampling time to be of much value within an isolator. Better to use passive samplers such as settle plates or settle bottles. Any contamination should be a cause for concern.
- RODAC's should be used at the end of the operation so you don't have to worry about residual media being present.
- In reality, are isolators sterile? Probably not - there is a shadowing of surfaces from gaskets, seals, etc.
- However, the detection of an organism in an isolator should be a cause for immediate concern and one may have to consider action against the product.

Determining Whether a Product Can be Terminally Sterilized: Jeanne Moldenhauer, Ph.D., Fujisawa, USA

FDA expects products to be terminally sterilized rather than aseptically filled whenever possible. With new products, it is not always an easy decision , so Fujisawa has developed an internal guideline as follows:

- Exemptions: Biologicals, lyophilized products, protein drugs, and dosage forms with preservatives cannot be terminally sterilized.
- A literature review is the next step if the product doesn't fall into the exemption category.
- If there is no literature available on the product to say whether it is steam sterilizable, they then go to a thermostability evaluation (various temps for various exposure times).
- If they find a time/temp that will work, they continue on to container/closure evaluation and product review to determine cycle parameters.

Update on PDA Aseptic Processing Activities: Russell Madsen, PDA, and James Agallaco

As mentioned earlier, Tech Report #22 will be issued soon. It will replace PDA Tech Reports 2 and 6. There is harmonization, but statistical media fill approach in the ISO/TC 198 or ISO/DIS 13408-1 draft are in conflict with the PDA document and would not be appropriate with FDA.

Key sections are 1) the media fill contamination limit should *approach* zero and 2) the dichotomy between sterility (absence of viables) and any media fill test limit greater than zero. Because media fills are different than product fills, it is hard to have them set at zero positives. Strategies you can use are:

(cont. pg. 8)

(PDA Highlights, cont.)

a) Set the contamination rate at an absolute value (e.g. 0.1%).
b) Use a full statistical approach with a 95% confidence level, or
c) Use acceptance criteria appropriate for the processing technology. This is the approach PDA has chosen.

From the Aseptic Fill survey, due out in January, were the following highlights:

a) Inert gassing - most people use TSB and air, but few use nitrogen or other gases.
b) use the actual production equipment for the media fill, rather than dedicated equipment.
c) Test interventions - 50% change the fill needle as an intervention in a media fill.
d) use 30-35°C for the incubation temperature
e) Most people believe that the source of media fill contamination is personnel-related.

The USP is currently working on a draft chapter for Container/Closure Integrity.

FDA Perspective: Kenneth Muhvich, Ph. D. CDER

He discussed the attributes of a microbial challenge container/closure integrity test that FDA would like to see:

- Test a representative number of samples
- Use a small motile bacterium for the challenge (such as *P.diminuta*).
- There should be a high number of viable bacteria at the end of the challenge period.
- Use a worst case container size, or bracket the container size.
- Test for each stopper formulation (they are not worried about the glass changing very much).
- Positive controls - All breached units should be contaminated.
- Use appropriate test/incubation conditions to grow the organism.
- Describe any adverse conditions (e.g. vacuum or pressure).
- Use of container/closure studies to demonstrate maintenance of sterility during stability testing.

In a complete reversal of policy, the agency now prefers the use of container/closure integrity testing in lieu of sterility testing, but at the present time, they must accept both. As he stated, "The theory of spontaneous generation was put to rest by Pasteur...". They prefer the microbial ingress test over dye immersion, and that it be performed on the actual drug product. However, they recognize that the nature of the product, or its antimicrobial properties or presence of preservatives might not make that test practical. They also prefer that the vial be tested inverted, since you are looking for the integrity of the container closure.
A draft guideline will be published next year, supported by all 4 agency divisions entitled "Container/Closure Integrity Testing in Lieu of Sterility Testing".

PMF Newsletter is published quarterly by the Pharmaceutical Microbiology Forum. 3166 Wood Valley Road, Panama City, FL 32405. Telephone (904) 763-5453. Send all inquires, letters, and comments to the above address, c/o L. Valdes-Mora.

PURPOSE: To provide a forum for discussion of microbiology issues in the pharmaceutical industry.
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Advertisements:

The PMF newsletter will accept advertisements for both those seeking employment, as well as those with current job openings. We also encourage any advertisements for products or items that are new and of interest to microbiologists. Please send these to Laura Valdes-Mora.

(Regulatory Compliance cont.)

1) Validated agar melt technique

2) Record keeping requirements

3) Review process

Each company should have the following procedures as part of their Master Plan:

Clean Room and Isolator(s)

1) Sterilizing Unit(s)
2) Depyrogenation Ovens(s)

3) Constant temperature water bath(s) (used for LAL gel clot

4) USP Purified Water System(s)

5) Incubator(s) (Mapped)

6) Disinfectant Validation

7) Automated Microbial Identification Systems

8) Agar melt cycles

9) Media storage

10) Computer systems

Regulatory Review Process

1) Have pre-approved protocols with acceptance criteria.

2) Installation Qualification (IQ) should include equipment ID, utilities and safety information.

3) Operational Qualification (OQ) should include calibration, maintenance, operation and cleaning.

4) Determine if protocol(s) were executed as written. Are they accurate? Do drawings (if any) correspond.

5) Determine if the protocol is based on sound and current scientific principles.

Change Control

1) Have pre-change evaluation approval.

2) Determine responsibility of resulting action plan.

3) Follow-up on the completion of tasks.

4) Review and approve equipment to be put back into use.

Support Systems

The following is a list of support systems for Microbiology laboratories:

1) SOP's

2) Equipment Calibration

3) Preventative Maintenance program

4) Computer validation

5) Sample handling, tracking

6) Data reporting

7) Data archives

8) Housekeeping of benches, hoods, floors, equipment, etc.

9) Environmental monitoring programs for sterility testing area and general laboratories.

10) Reagent, solution, and disinfectant control.

11) Temperature monitoring.

12) Water monitoring

Raw Data Support Documentation

1) Authentic, controlled, reviewed, secure.

2) Accurate, complete, matches application.

3) Environmental summaries, identifications.

4) Changes explained and counter-witnessed.

General Training

1) Documented, periodic, effective.

2) Sufficient supervision, experience.

3) Personnel experience, education

4) Syllabus

5) Sampling technique

Quality Control

1) Have aberrant-out of specification (OOS) investigation policy.

2) Pursue identification of pathogenic/objectionable organisms.

(cont. pg. 10)

(Regulatory Compliance cont.)

1) Historical summary reports.

2) Contamination confinement, source.

3) Raw material excipient testing.

4) Quality audit trending.

Looking at the future, one could envision:

1) Harmonization

2) More clear guidance.

3) Manufacturing controls applied to laboratories.

4) More detailed requirements in procedures.

5) Bar coding (to be used in testing)

Pharmaceutical Microbiology Forum (PMF) 1996 Organizational Board

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Calendar of Events

The Calendar of Events is provided as a service to PMF Newsletter readers. Submission of complete and accurate information will be published on a space-available basis.

April 15-16, 1997, *Moving Pharmaceutical Microbiology into the 21st Century,* AAI, Wilmington, North Carolina.

May 12-14, 1997, *cGMP for Pharmaceutical Quality Control Laboratory Personnel,* Center for Professional Advancement, Chicago, Illinois.

May 15-16, 1997, *Validation and Certification of the Pharmaceutical Quality Control Laboratory,* Center for Professional Advancement, Chicago, Illinois.

Future Topics

The purpose of the Newsletter is a sharing of information among Microbiologists. Your contributions to *PMF Newsletter* are needed in the form of short articles, letters to the Editor, job openings, comments, or suggestions. Please direct your correspondence to *PMF Newsletter,* c/o L. Valdes-Mora, 3166 Wood Valley Road, Panama City, FL 32405 [Tel (904) 763-5453]. Submit any articles with your name and phone number in case we need to contact you. Your name and company will not appear without prior written authorization.

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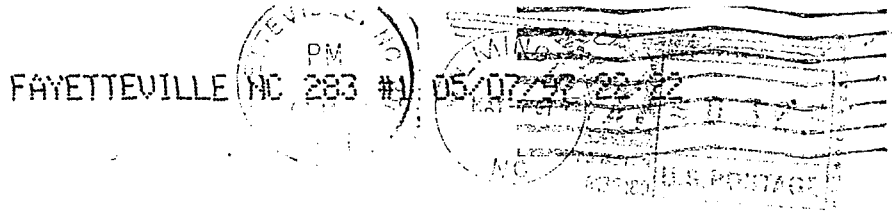

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