

# PMF Newsletter

A quarterly publication of the Pharmaceutical Microbiology Forum

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

The information contained in this newsletter is the professional opinions of our members and does not represent the policies or operations of any corporation or government agency to which members may be associated. *PMF Newsletter* is intended to serve as an open forum and confidentially will be maintained. The information in *PMF Newsletter* is solely for information purposes and is developed from sources believed to be reliable. Statements expressed constitute current opinions derived through analysis of available information and professional networking. Articles or opinions are for information only for PMF members to stimulate discussion and are not the views of the PMF board or regulatory agencies. The *PMF Newsletter* cannot make any representations as to the accuracy or completeness of the information presented and the publisher cannot be held liable for errors.

## President's Message

Systematics, the science which deals with naming organisms, also referred to as nomenclature, has not had too much impact in our industry. However, now in the 90's, the trend toward reclassifying microorganisms into new genera, particularly bacteria, is touching industrial microbiologists.

The members of the genus, *Pseudomonas* ended in one of three genera (*Pseudomonas*, *Brevundimonas*, and *Burkholderia*). *Pseudomonas diminuta* is now *Brevundimonas diminuta* while *Pseudomonas picketti* is reclassified as *Burkholderia picketti*. These changes are usually published in the *International Journal of Systematic Bacteriology*. According to one of the technical experts at bioMerieux-Vitek, reclassifications are more common than we may be aware of in the pharmaceutical microbiology arena. However, if the new name is not widely used, it may disappear and databases nor literature are changed. The bio-Merieux Vitek representative indicated that he normally sees a lag time of 2 years from the time the new name is published to the time it becomes common knowledge.

The change of genus for *P. picketti* fueled several discussions in the Internet. As a result, I was asked to obtain the journal reference for this change. The search ended with a surprise twist of events. *B. picketti* has once again been reclassified and it was published in the *International Journal of Systematic Bacteriology* Volume 6, Number 2, Page 625, April 1996. The new name is *Ralstonia picketti*. Would this ever become popular?

The genus *Micrococcus* has also experienced a few changes. *Micrococcus roseus* is now *Kocuria rosea* and *Micrococcus varians* is *Kocuria varians*. Also, *Enterobacter agglomerans* is now known as *Pantoea agglomerans*.

How much more difficult would it be to trace the origin of a contaminant? The first thing that comes to mind with all these changes, is that we all must ensure that changes in Systematics are covered in the appropriate Microbial Identification Standard Operating Procedure (SOP) at your company. In addition, it may be useful to add the former name or names to the SOPs. This can be very valuable in the future during a failure investigation requiring identification and tracking of source(s) of contamination.

Laura



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The PMF would like to thank Nancy Truluck who has been our Assistant Newsletter Editor for the past several years. She has done a fine job, dedicating many hours of her own time for the benefit of other microbiologists. Thank you, Nancy for your time and hard work. We'll miss you. All of us with the PMF.

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### *The Microbiology BBS*

Scott Sutton , Ph.D.

*The Microbiology BBS* has two services available, the Microbiology BBS (a telnet BBS service), and the Microbiology Network. The Microbiology Network website (<http://www.microbiol.org>) contains a great deal of information of interest to microbiologists, with special emphasis on industrial applications. The objective of this service is to act as a means of information exchange among microbiologists in industry and academics. Some of the offerings available at this site include:

- User groups  
This service has proven very popular. We provide free web sites, and will be providing free Email list services to microbiology- and biotechnology-related user's groups. We will be adding Email lists and web sites for as many as we can.  
For more information:  
<http://www.microbiol.org/usrgroup.htm>
- Please contact [sysop@microbiol.org](mailto:sysop@microbiol.org) if you belong to a user's group that would like to establish a free web page and/or mail list.

- **Mail Lists**  
The Microbiology Network offers mailing lists to interested groups. A mail list can be thought of as a discussion group carried out over Email. A list is established on any topic of interest to the users. This is serviced by a listserver on our site, and promoted on The Microbiology Network web site. The Listserver handles all messages to the forum *via* Email across the Internet, and disseminates the messages back to the discussion group members *via* Email. One of our most popular mail lists is devoted to the PMF, but open to the public.

For more information:

<http://www.microbiol.org/pmflist.htm> - PMF Mail list

<http://www.microbiol.org/mailist.htm> - Microbiology/Biotechnology related mail lists

Please contact [sysop@microbiol.org](mailto:sysop@microbiol.org) if you would belong to a user's group that would like to establish a free mail list.

- **Web page services**  
Web pages are available for consultants and companies (large and small). We also provide space for web pages announcing upcoming courses.

For more information:

<http://www.microbiol.org> - The Microbiology Network

- **Resources**  
Information on services, equipment, activities, contract laboratories, and consultants is available.
- **The Virtual Library: Microbiology & Virology**  
The Virtual Library is a project run by CERN to index all stable web sites. We are responsible for the Microbiology section, and appreciate all suggestions for new web sites or new categories (Email your list of favorite sites to [vlmicro@microbiol.org](mailto:vlmicro@microbiol.org)).

For more information:

- [http://www.microbiol.org/vl\\_micro/index.htm](http://www.microbiol.org/vl_micro/index.htm) - Virtual Library: Microbiology & Virology

- [http://microbiol.org/vl\\_micro/vl\\_assoc.htm](http://microbiol.org/vl_micro/vl_assoc.htm) - Associations

- [http://microbiol.org/vl\\_micro/vl\\_collc.htm](http://microbiol.org/vl_micro/vl_collc.htm) - Culture Collections

- [microbiol.org/vl\\_micro/vl\\_dbase.htm](http://microbiol.org/vl_micro/vl_dbase.htm) - Databases

- [microbiol.org/vl\\_micro/vl\\_educ.htm](http://microbiol.org/vl_micro/vl_educ.htm) - Education Sites

- [microbiol.org/vl\\_micro/vl\\_jrnal.htm](http://microbiol.org/vl_micro/vl_jrnal.htm) - Journals

- [microbiol.org/vl\\_micro/vl\\_govt.htm](http://microbiol.org/vl_micro/vl_govt.htm) - Government and Regulatory Sites

- [microbiol.org/vl\\_micro/vl\\_image.htm](http://microbiol.org/vl_micro/vl_image.htm) - Microbiology Images

- [microbiol.org/vl\\_micro/vl\\_med.htm](http://microbiol.org/vl_micro/vl_med.htm) - Medical Microbiology

- [microbiol.org/vl\\_micro/vl\\_univ.htm](http://microbiol.org/vl_micro/vl_univ.htm) - University Departments

- [microbiol.org/vl\\_micro/vl\\_viol.htm](http://microbiol.org/vl_micro/vl_viol.htm) - Virology

- [microbiol.org/vl\\_micro/vl\\_prot.htm](http://microbiol.org/vl_micro/vl_prot.htm) - Protista

- [microbiol.org/vl\\_micro/vl\\_rsorc.htm](http://microbiol.org/vl_micro/vl_rsorc.htm) - Other Resources

(Mail Lists, Bulletin Board Systems, User Groups, and Newsgroups)

- **Bulletin Board Services - *The Microbiology BBS***

*The Microbiology BBS* is operated as a telnet BBS, that is to say that anyone can access it who is on the Internet (telnet: [microbiol.org](http://microbiol.org)). This allows us to offer a variety of services to microbiologists logging in to the system. The system is much more convenient when using the special software available for downloading from the main site (<http://www.microbiol.org/mbbs.htm>)

- **Files**

We currently offer the largest specialized microbiology and biotechnology file collection available.

If you have software that you would like to make available, please upload it to the BBS, or Email it to [sysop@microbiol.org](mailto:sysop@microbiol.org). Types of files currently offered include microbiology, biology, medical, games (biology-related), general science, biotechnology, biochemistry, statistics, health, utilities, and many others. Descriptions of the file libraries may be found at

<http://www.microbiol.org/files.htm>.

We also maintain the PMF Library. The PMF library contains back issues of the PMF newsletter, available to members of PMF for downloading.

- Chat  
Teleconferences are available for regularly scheduled, real-time discussions. Individuals or groups interested in hosting public or private conferences should contact the sysop (sysop@microbiol.org) for details.
- Email  
All users of the BBS have the opportunity to have an Internet Email address from the system ("yourname"@microbiol.org).
- Vendor Showcase  
This area is set aside for vendors to "display" new products and software. Document databases, images of new products, demonstration versions of software, and new product announcements are encouraged. Please upload any demo software, or product information.
- Email List Archives  
Several popular Email lists are archived on the BBS. You may participate on these from the BBS, without having to subscribe personally and receive all that Email. You can also review past postings from the list online.

These services are offered free of charge to the user, supported by corporate sponsorship to The Microbiology Network.

We would like to take this opportunity to thank our corporate sponsors (in alphabetical order):

- AAI - Testing services to the pharmaceutical microbiology community.
- Celsis - Leaders in ATP bioluminescent technology for food, water, and pharmaceutical microbiology.
- Chemunex - Introducing a real-time, quantitative viable count methodology for microbial analysis of foods, dairy products, pharmaceuticals, and water.

Scott Sutton, PhD, is the owner of *The Microbiology BBS*, an information provider since 1995. He is also Assistant Director of R&D Microbiology for Alcon Laboratories, and serves on the USP Microbiology Subcommittee.

### **Regulatory Issues Associated with Quality Control in Microbiology Laboratories**

The following is a summary of a presentation at a microbiology seminar held in Wilmington, NC in April 1997.

#### *General Information*

- FDA started issuing 483's in 1953
- Respond promptly to 483's
- Present a timetable with any corrections that will be implemented

#### *Examples of 483's*

- Incomplete records
- Non- validated methods
- Lack of calibration (autoclave, hot air ovens)
- Inadequate ventilation (no air quality tests performed)
- Non- validated filtration process
- Inadequate monitoring during aseptic processes
- Inadequate employee practices. Aseptic techniques not used by employees. Training not documented nor reinforced (no retraining)
- Isolates not identified
- Own procedures not followed
- Lack of SOPs for environmental monitoring of the microbiology laboratory
- Poor record-keeping (temperature of incubators and refrigerators not recorded)

- Lack of equipment qualification (failure to validate sterilizer)
- Unacceptable procedure (retesting until acceptable results obtained and reporting only good results)
- No investigations or reason for failures identified
- Bioburden testing not followed by identification of isolates
- Improper calibration of balances (5 gram weights used for calibration of balance routinely used for samples of 1 gram or less weight)
- Firm failed to evaluate existing microbiological procedures
- SOP calls for use of clean room. Test performed in isolator. Product impact of this change not investigated.
- No records of temperature for waterbaths
- Re-using temperature charts
- Inadequate laboratory space
- No record of calibration of pH meter

### Conclusions

1. The items under the 483 section generally caused the tested products to be considered adulterated.
2. The 2 most common observations during the past year were not validating methods and not identifying organisms.
3. Some of the observations were for contract laboratories. It is important that any company using a contract laboratory audits the testing facility regularly (usually once per year).

### *CFR GMP Sections that apply to microbiology laboratories are as follows:*

- |           |                               |           |                     |
|-----------|-------------------------------|-----------|---------------------|
| • 211.25  | Education and Training        | • 211.160 | Laboratory Controls |
| • 211.42  | Adequate Space                | • 211.167 | Special Testing     |
| • 211.46  | Ventilation                   | • 211.194 | Records             |
| • 211.113 | Microbiological Contamination |           |                     |

### **Computer Validation**

#### *Security Questions*

- Are passwords being changed often for equipment or LIMS?
- Are passwords written down?
- Is a virus protection program plan in place and what happens if a virus is detected?
- Is personal software loaded on the terminal?
- Can electronic data be changed?

#### *Audit of software vendor*

- Who wrote the software? Do the people still work for the company and what are their qualifications?

- Where is the source code stored and is it accessible if the FDA needs to see it?
- Will the vendor permit an audit, especially if several copies of software are purchased?
- Is the vendor willing to make changes that are requested?

### Upcoming USP Events

- May 4-5, 1998, USP Open Conference on 'Microbiology for the 21<sup>st</sup> Century', at the Hyatt Regency in New Orleans, Louisiana. For further information or to register, see the web site: [www.usp.org/symposium\\_003.htm](http://www.usp.org/symposium_003.htm).

The PMF recommends that you *write to the USP with your comments on all proposals*. You can write representing your company, or as a single *scientist*.

### 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.*

- December 2-5, 1997. PDA Education Courses, Boston, MA
- December 4-5, 1997. The Institute for Applied Pharmaceutical Sciences- 'The FDA Investigator Cometh', San Francisco Bay area, CA
- December 8-10, 1997. The Institute for Applied Pharmaceutical Sciences- 'Current Good Manufacturing Practice (cGMP) for Pharmaceutical Quality Control Laboratory Personnel', Boca Raton, FL

### Future Topics

The purpose of the Newsletter is a sharing of information among Microbiologists. Your contributions to the *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 (850) 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.

### 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. There is no fee for the placements. All material is subject to approval by the Board of Directors.

Please send these to Laura Valdes-Mora.

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### Current Compendia

US Pharmacopoeia (USP) 23 Supplement 7 (November 15, 1997)

European Pharmacopoeia (EP) 1997

European Pharmacopoeia (EP) Supplement 1998

Japanese Pharmacopoeia (JP) 1996

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\* If you use any other compendia, let us know for inclusion in this corner

### The following Internet Sites may be of interest to you:

Internet Address	Description
<a href="http://thorplus.lib.purdue.edu:8100/gpo/">http://thorplus.lib.purdue.edu:8100/gpo/</a>	Purdue University Library Depository of Government Documents (including Federal Register)
<a href="http://www.fda.gov/cdrh/comp/swareval.html">http://www.fda.gov/cdrh/comp/swareval.html</a>	Draft FDA 'General Principles of Software Validation'
<a href="http://www.fda.gov/opacom/morechoices/industry/guidance/gelguide.htm">http://www.fda.gov/opacom/morechoices/industry/guidance/gelguide.htm</a>	CDER Guidance on BSE
<a href="http://www.speedupfda.com">http://www.speedupfda.com</a>	Former FDA Reviewer's ideas on actions and strategies to reduce FDA approval time
<a href="http://www.fda.gov/cder/drug.htm">http://www.fda.gov/cder/drug.htm</a>	FDA Documents such as the 'Orange Book' ("Approved Drug Products with Therapeutic Equivalence Evaluations-17th ed.)
<a href="http://www.ifpma.org5.html">http://www.ifpma.org5.html</a>	ICH Home page and Guidelines
<a href="http://www.gbf-braunschweig.de/DSMZ/bactnom/bactname.htm">http://www.gbf-braunschweig.de/DSMZ/bactnom/bactname.htm</a>	Up-to-date info reference on species and taxonomy
<a href="ftp://ftp.cict.fr/pub/bacterio/">ftp://ftp.cict.fr/pub/bacterio/</a>	<i>International Journal of Systematic Bacteriology</i>
<a href="http://www.biolog.com">http://www.biolog.com</a>	Biolog Home page- contains useful microbiological links
<a href="http://www.fda.gov/cber">http://www.fda.gov/cber</a>	CDER Home page
<a href="http://www.microbiol.org">http://www.microbiol.org</a>	Microbiology network

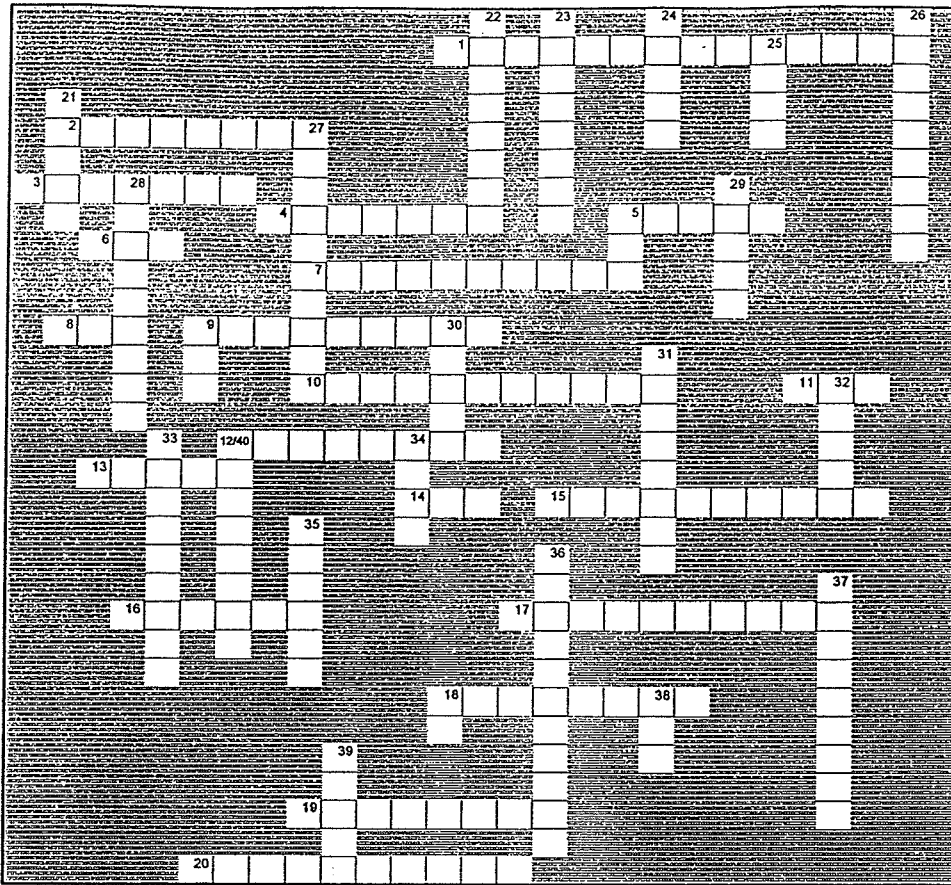
If you have found an Internet site that contains information of relevance to pharmaceutical microbiology, please let us know.

**Come Visit Our Website at <http://www.microbiol.org/PMF.htm>**

**Are you aware of our on-line discussion group? Membership is FREE. To join, send an e-mail to [PMFList @ microbiol.org](mailto:PMFList@microbiol.org). Under 'subject' type "Subscribe". You can ask, answer, or read questions of and comments from your colleagues.**

**NOTE: PMF Membership Salary Survey is currently being tabulated and will appear in the next issue of the PMF Newsletter.**

# Crossword Puzzle



## Across

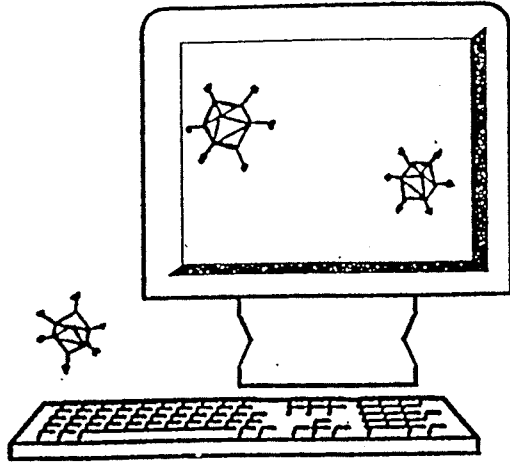
1. Used in the Wirtz-Conklin Stain
2. Lactose fermentor
3. Cytoplasmic genetic element not integrated into the chromosome
4. Genus that exhibits swarming motility
5. Forms 'grape-like' clusters
6. USP 23 <85>
7. Genus often found in eggs and poultry
8. 100X lens requires this
9. Sterilization device
10. Exotoxin causing Staph food poisoning
11. Report plate counts as this
12. Enzyme which degrades hydrogen peroxide
13. Bacterial virus
14. 20E is an example of this kit
15. Tetracycline, for one
16. Manufacturer who uses tetrazolium dye for identification
17. Non spore-forming state
18. H<sub>2</sub>O<sub>2</sub>
19. Long whip-like organelles of locomotion
20. A type of cell with no nuclear membrane and a haploid state (bacteria and blue-green algae)

## Down

5. Plate Count Agar (abbr.)
9. Microbiology professional association (abbr.)
18. Measurement of hydrogen ion concentration
21. Ground beef contaminant
22. Spore-forming genus
23. Disease-causing organism
24. bio-Merieux \_\_\_\_\_
25. Christian \_\_\_\_\_ developed this differential stain
26. LPS
27. Anton von Leeuwenhoek discovered 'animalcules' using this instrument
28. USP <71> test
29. Clostridium species can produce this structure
30. Parvo, for example
31. Used for negative staining
32. Molds, for example
33. Salt-loving
34. Solidifying Agent
35. *Yersinia pestis* is responsible for this epidemic
36. Genus commonly found in water
37. Whooping-cough
38. Double-helix
39. Cellular hair-like outgrowths used for movement
40. Plants and bacteria share this structure

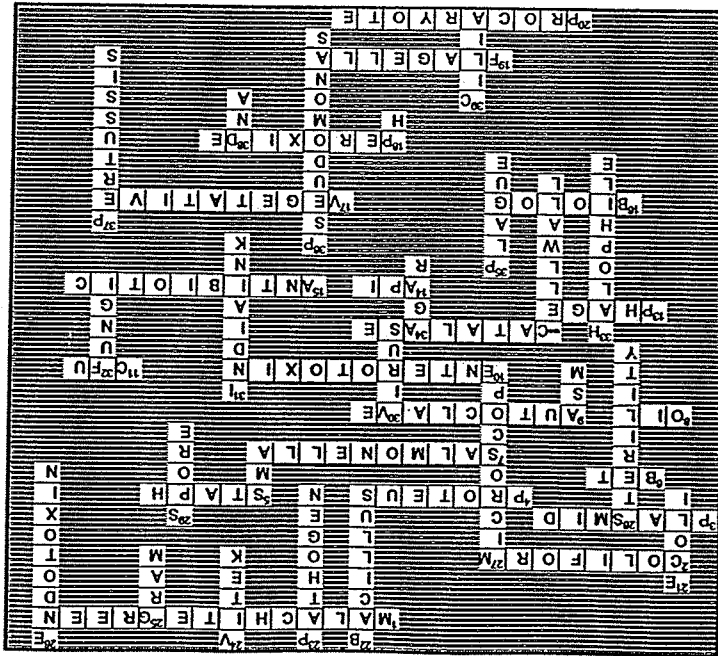


# MICROTOON



DO YOU THINK IT'S THE FLU?  
*AK*

## Crossword Puzzle Solution



Pharmaceutical Microbiology Forum

Membership Application  
or  
Change of Information Form

**MISSION:** The PMF provides a forum for pharmaceutical microbiologists to exchange information on microbiological issues in the pharmaceutical industry and interact with the USP and regulatory agencies.

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THIS APPLICATION IS:

A New Member Application	<input type="checkbox"/>
To Update my information, as indicated	<input type="checkbox"/>

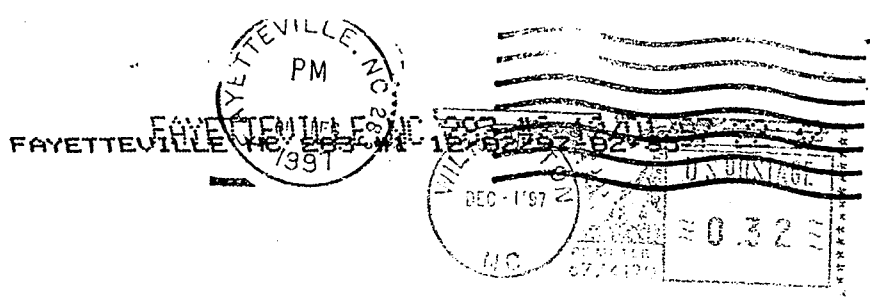
Name: \_\_\_\_\_  
Company: \_\_\_\_\_  
Department: \_\_\_\_\_  
Position (title): \_\_\_\_\_  
  
Phone: \_\_\_\_\_  
Fax: \_\_\_\_\_  
e-mail Address: \_\_\_\_\_  
  
Preferred Mailing Address  
Co.: \_\_\_\_\_  
Address: \_\_\_\_\_  
  
City, State \_\_\_\_\_  
Country: \_\_\_\_\_  
Zip \_\_\_\_\_  
  
Please tell us how you heard about us: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

The PMF mailing list is private, not for sale.  
Membership dues are a one time fee of \$15.00. Please send check or money order to the address below.

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c/o Ms. Elizabeth A. Darner  
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Pharmaceutical Microbiology Forum  
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Address Correction Requested

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