



Maryland Department of Agriculture

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Office of Marketing
Animal Industries and Consumer Services

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December 1, 2020

RE: **REMINDER TO SUBMIT VFDS AND PRESCRIPTION RECORDS FOR MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS**

Dear Maryland Veterinarian:

This is a reminder to submit your VFD and prescription records for medically important antimicrobial drugs prescribed to large cattle, swine and poultry operations to the Maryland Department of Agriculture.

- **Records prescribed through September 30th, 2020 are due October 30, 2020, and are OVERDUE if you have not submitted them.**
- Records prescribe thru October 1 thru December 31, 2020 are due January 31, 2021.

Instructions for submitting these records were provided May 22, 2020 and are attached [HERE](#). Medically important antimicrobial drugs are those listed in "Appendix A" of the U.S. Food and Drug Administration's Guidance for Industry #152, provided below.

Maryland Senate Bill 471, passed in April 2019, **requires licensed veterinarians** to submit all copies of Veterinary Feed Directives (VFD) and copies of prescriptions issued beginning January 1, 2020, to the Maryland Department of Agriculture (MDA) for any medically important antimicrobial drugs in feed or water prescribed to cattle, swine or poultry herds or flocks that have the following number of animals:

- (1) Cattle on a farm operation that sells 200 cattle or more per year;
- (2) Dairy cattle on a farm operation with a herd size of 300 or more dairy cattle;
- (3) Swine on a farm operation that sells 200 swine or more per year; or
- (4) Poultry on a farm operation that sells 60,000 birds or more per year.

The Secretary may impose an administrative penalty, not exceeding \$2,000 per violation, on a person that violates this subtitle. We strongly encourage you to submit your records on time. If you have any questions regarding these requirements, please call Dr. Jo Chapman at 410-841-5810 or njo.chapman@maryland.gov.

Sincerely,

Michael J. Odian, DVM
State Veterinarian

Attachments (2)

How to Submit Rx and VFD Records to Maryland OneStop

1. Go to <https://onestop.md.gov/> and search for “Free VFD”.
Alternatively, you can go to <https://bit.ly/mda-vfd-rx-upload> to get directly to the online form.
Consider bookmarking this page in your web browser.
2. Enter your OneStop username and password. If you have not created an account, you will have to do so by selecting **Register**.
3. Select **Apply Online**.
4. At the prompt “**Would you prefer to upload a complete, paper VFD or input your VFD information below**”? Select which of the two methods you want to use for reporting your VFD:
 - **Upload VFD or Prescription**
If you already have a digital version, you can upload it. If you have a printed VFD or RX, you can scan it as a PDF using a scanner or a mobile phone app. Then select this option and select **Choose Upload** for a prompt to upload your VFD file.
 - **Input VFD information**
If you haven’t already written the RX or VFD yet, select this option to input the VFD or RX data. At the end of entering the relevant information, you can save the completed VFD as a PDF for sending to appropriate recipients.

To view and print your VFD to a PDF file that you can distribute, select the **Print** option.

If you select Submit before printing and still wish to print the VFD, you can do so by following the steps below:

How to View or Print A VFD or Prescription That You Have Submitted

1. Make sure you are logged into OneStop.
2. Select **My Dashboard**.
3. Under *Your Recent Applications*, select the link labeled “**Free VFD Form and Prescription Upload**” that corresponds to the VFD that you want to view.
4. View the completed VFD or prescription. You can print the VFD by selecting **Print**.

How to Upload or Submit Another VFD

In your browser, select the bookmark that you created when first starting out. Doing so brings you back to the page with the **Apply Online** step. Alternatively, you can search on the main Md OneStop page for “Free VFD”.

Having Trouble?

If you are having trouble uploading your document or filling out the online VFD, use the Contact Us link or email directly at onestop.support@maryland.gov and let us know. We’ll get back with you quickly.

Appendix A

Ranking of antimicrobial drugs according to their importance in human medicine

Objective: This appendix describes a process for ranking antimicrobial drugs with regard to their relative importance in human medicine. FDA recommends this ranking be considered when completing the *hazard identification* and the *consequence assessment* portions of the qualitative risk assessment outlined in this guidance document. The general criteria for determining the importance ranking are outlined and a preliminary listing of various antimicrobial drugs and assigned rankings is provided.

Ranking process: Based on a consideration of the factors described below, specific antimicrobial drugs or classes of antimicrobials should be ranked as to whether they are critically important, highly important, or important to human medical therapy. The assignment of a ranking to a given antimicrobial or class of antimicrobials is dependent upon the degree to which any one or more of the factors described below is applicable to the drug in question. Table A1 provides a ranking based on a consideration of the criteria described below.

The possible importance rankings are defined as follows:

Critically Important: Antimicrobial drugs which meet BOTH criteria 1 and 2 below.

Highly Important: Antimicrobial drugs which meet EITHER criteria 1 or 2 below.

Important: Antimicrobial drugs which meet EITHER criterion 3 and/or 4 and/or 5.

Note: Table A1 does not necessarily include all antimicrobial drugs or drug classes. The development of new antimicrobials for human therapy, the emergence of diseases in humans, or changes in prescribing practices, etc., are among the factors that may cause the rankings to change over time. Therefore, it is the intent of the Agency to reassess the rankings provided in Table A1 periodically to confirm that the ranking is consistent with current circumstances. The rankings of drugs in Appendix A may be subject to change at any time when information becomes available that would impact those rankings. The sponsor may wish to consult with FDA regarding the ranking relevant to their proposed drug at the time the assessment is made.

Criteria considered in ranking process: In developing criteria for ranking antimicrobial drugs with regard to their importance in human medicine, the FDA considered broad issues associated with the efficacy of drugs in human medicine and factors influencing the development of antimicrobial resistance. Specific factors include the usefulness of the drug in food-borne infections, the types of infections treated, the availability of alternative therapies, the uniqueness of the mechanism of action, and the ease with which resistance develops and is transferred between organisms. Note that multiple factors may be applicable to some products, illustrating their considerable importance to human medicine. We recommend that drug sponsors use the

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following criteria to rank the importance of drugs in human medicine. The criteria are ranked from most to least important, e.g. criterion 1 is the most important.

1. *Antimicrobial drugs used to treat enteric pathogens that cause food-borne disease*

The Infectious Disease Society of America (IDSA) guidelines on the treatment of diarrhea and other sources such as the Sanford Guide provide the drugs typically used in the treatment of food-borne diseases.

2. *Sole therapy or one of few alternatives to treat serious human disease or drug is essential component among many antimicrobials in treatment of human disease.*

- A. Includes antimicrobials like vancomycin and linezolid for MRSA infections. Although they are not the “sole” therapy, they are one of only a few alternatives.
- B. This would also include a drug like polymyxin where it is one of few alternatives for multi-drug resistant *Pseudomonas aeruginosa* infections.
- C. Rifampin is not only a drug used to treat TB but also it is an essential part of the treatment regimen as the cure rate is lower without it.
- D. Serious diseases are defined as those with high morbidity or mortality without proper treatment regardless of the relationship of animal transmission to humans. For example, rifampin is an essential drug to treat disease caused by *Mycobacterium tuberculosis* (high morbidity and mortality if untreated) even though this is a human pathogen. Gonorrhea occurs only in humans and is not lethal but can result in sterility if left untreated (high morbidity).

3. *Antimicrobials used to treat enteric pathogens in non-food-borne disease*

Enteric pathogens may cause disease other than food-borne illness. For instance, *E. coli*, which causes food-borne disease, is also capable of causing diseases as diverse as urinary tract infections and neonatal meningitis.

4. *No cross-resistance within drug class and absence of linked resistance with other drug classes*

- A. Absence of resistance linked to other antimicrobials makes antimicrobials more valuable. An example is quinolone resistance in pneumococci, which currently does not appear linked to penicillin resistance. On the other hand, penicillin resistance appears to be linked to macrolide, tetracycline, and trimethoprim-sulfamethoxazole resistance in pneumococci.
- B. Cross-resistance within antimicrobial classes and absence of linked resistance may change over time and will need to be updated periodically.
- C. In this context, “cross-resistance” refers to the transmission of resistant determinants between bacterial species or genera and does not refer to transmission of resistant organisms between animals and humans. This is addressed in the release assessment part of the guidance.

5. *Difficulty in transmitting resistance elements within or across genera and species of organisms*

- A. Antimicrobials to which organisms have chromosomal resistance would be more valuable compared to those antimicrobials whose resistance mechanisms are present on plasmids and transposons.
- B. This does not refer to “ease of transmissibility” from animals to humans of the resistant pathogen as this is addressed elsewhere in the guidance in the release assessment.

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Table A1: Potential ranking of antimicrobial drugs/drug classes based on the identified relevant factors. C- Critically important; H- Highly important; I – Important.

	Classification	1) Enteric pathogen responsible for food-borne disease	2) Sole/limited therapy or essential therapy for serious disease (See "Comments" for examples)	3) Used to treat enteric pathogens in non-food-borne disease	4) No cross-resistance within class/no linked cross-resistance with other classes	5) Limited risk of transmission of resistance elements within/across species of organisms	Comments
Natural penicillins	H		X				Neurosyphilis: Serious infection due to Group A streptococci
Benzathine pen G							
Penicillin G							
Penicillin V							
Penase Resistant Pens	H		X				Serious infections due to <i>Staphylococcus aureus</i>
Cloxacillin							
Dicloxacillin							
Nafcillin							
Oxacillin							
Antipseudomonal Pens	H		X	X			Serious infections due to <i>Pseudomonas aeruginosa</i>
Mezlocillin							
Pipercillin							
Pipercillin/tazo							
Ticarcillin							
Ticarcillin/Clav							
Carbenicillin							
Aminopenicillins	H		X	X			Infections due to <i>Listeria monocytogenes</i>
Amoxicillin							
Ampicillin							
Ampicillin/Sulbacta							
1st Gen Ceph	I			X			
Cefazolin							
Cafadroxil							
Cephalexin							
Cephradine							
2nd Gen Ceph	I			X			
Cefaclor							
Cefaclor-CD							
Cefamandole							
Cefonacid							
Cefprozil							
Cefuroxime							
Loracarbef							

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	Classification	1) Enteric pathogen responsible for food-borne disease	2) Sole/limited therapy or essential therapy for serious disease (See "Comments" for examples)	3) Used to treat enteric pathogens in non-food-borne disease	4) No cross-resistance within class/no linked cross-resistance with other classes	5) Limited risk of transmission of resistance elements within/across species of organisms	Comments
3rd Gen Ceph	C	X	X	X			Meningitis: Necrotizing enterocolitis
Cefdinir							
Cefixime							
Cefoperazone							
Cefotaxime							
Cefpodoxime							
Ceftazidime							
Ceftibuten							
Ceftizoxme							
Ceftriaxone							
4th Gen Ceph	H		X	X			Sole agent approved for use as empiric monotherapy for neutropenic fever
Cefepime							
Cephamecins	I			X			
Cefotetan							
Cefoxitin							
Carbapenems	H		X	X			Infections due to multidrug resistant gram negative rods
Imipenem							
Meropenem							
Ertapenem							
Monobactams	I			X			
Aztreonam							
Quinolones	I				X	X	
Nalidixic Acid							
Cinoxacin							
Oxolinic Acid							
Pipemidic Acid							
Flouroquinolones	C	X	X	X	X	X	Infections due to multidrug resistant gram negative rods
Norfloxacin							
Ciprofloxacin							
Ofloxacin							
Enoxacin							
Levofloxacin							
Lomefloxacin							
Sparfloxacin							
Grepafoxacin							
Gatifloxacin							
Moxifloxacin							

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	Classification	1) Enteric pathogen responsible for food-borne disease	2) Sole/limited therapy for or essential therapy for serious disease (See "Comments" for examples)	3) Used to treat enteric pathogens in non-food-borne disease	4) No cross-resistance within class/no linked cross-resistance with other classes	5) Limited risk of transmission of resistance elements within/across species of organisms	Comments
Aminoglycosides	H		X	X			
Amikacin							
Gentamicin							Enterococcal endocarditis
Tobramycin							Sole antimicrobial approved for aerosolized therapy in cystic fibrosis
Kanamycin							
Streptomycin							Infections due to <i>Mycobacterium tuberculosis</i>
Neomycin							
Netilmicin							
Spectinomycin							Infections due to <i>Neisseria gonorrhoeae</i> in pregnancy
Macrolides	C	X	X				Legionnaire's disease: MAC/MAI prophylaxis and therapy
Erythromycin							
Azithromycin							
Clarithromycin							
Clindamycin	H		X				Serious infections due to Group A streptococci: Alternative therapy of infections due to <i>Staphylococcus aureus</i> in patients with serious beta lactam allergy
Tetracyclines	H		X				Rickettsial disease: Anthrax therapy/prophylaxis
Tetracycline							
Chlortetracycline							
Demeclocycline							
Doxycycline							
Minocycline							
Glycopeptides	H		X				Infections due to methicillin resistant <i>Staphylococcus aureus</i>
Vancomycin							
Streptogramins	H		X				Infections due to vancomycin resistant <i>Enterococcus faecium</i>
Dalfopristin/quinupristin							

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	Classification	1) Enteric pathogen responsible for food-borne disease	2) Sole/limited therapy or essential therapy for serious disease (See "Comments" for examples)	3) Used to treat enteric pathogens in non-food-borne disease	4) No cross-resistance within class/no linked cross-resistance with other classes	5) Limited risk of transmission of resistance elements within/across species of organisms	Comments
Oxazolidones	H		X		X		Infections due to methicillin resistant <i>Staphylococcus aureus</i> and vancomycin resistant <i>Enterococcus</i>
Linezolid							
Pyrazinamide	H		X				
Isoniazid	H		X				
Rifamycins	H		X				
Rifampin							
Rifabutin							
Chloramphenicol	H	X		X			
Metronidazole	H		X				Infection due to <i>Clostridium difficile</i>
Trimeth/Sulfameth	C	X	X	X			Infection due to <i>Pneumocystis carinii</i>
Polymyxin B	H		X	X			Infections due to multidrug resistant gram negative rods

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