Ractopamine (Paylean™) Use in Show Pigs:
Show Management Considerations for 2020

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Ractopamine is the active ingredient in a feed additive that enhances growth in meat animals by repartitioning nutrients towards lean tissue growth and away from fat deposition. The FDA approved ractopamine use in market swine in 1999. While other countries have previously banned ractopamine use, it was China's decision to only import pork from ractopamine-free hogs that prompted several U.S. packers to capitalize on this large potential market and only accept hogs that were raised without the product in their diets. As a result, live swine shows and fairs may have less market access for market hogs being sold directly from the fair. Show pigs, although a small portion of the U.S. pork supply (approximately 1%), may still enter these markets, and must be able to meet the same market demands as commercial pigs.

For additional background information, colleagues Drs. Locke Karriker and Chris Rademacher from the Swine Medicine Education Center at Iowa State University's College of Veterinary Medicine have compiled an extensive document on the specifics of ractopamine's effects in the body, depletion, testing, and potential for cross-contamination available here: https://www.ipic.iastate.edu/information/RactopamineFAQ2020.pdf. Utilizing the information presented by Karriker and Rademacher, this document is intended to incorporate available information into the decision process for management of market hog exhibitions, fairs and shows by providing options for consideration.

Please note: each situation is different, there may not be an ideal option, and each show or fair must make the decision that works for their circumstances.

The Situation:

1) Ractopamine is a legal feed additive that, when used according to label instructions, is considered safe by the FDA for both pigs and humans consuming pork from these pigs.
2) Due to the effectiveness of the product, many swine exhibitors previously fed ractopamine to show pigs to enhance lean tissue growth and may still have some product on their premises, which may lead to cross-contamination.
3) It appears that cross-contamination of ractopamine can occur quite easily through exposure to urine, feces, bedding and of course, feed. Due to very low levels necessary to be effective, it has proven difficult to completely clean the areas and equipment that were previously in contact with ractopamine in order to prevent cross-contamination.
4) Ractopamine is a very large molecule and is easy to detect at very small levels, even below the FDA food safety or legal residue levels. Cross-contamination, even in carcasses from pigs not fed ractopamine, may result in a positive test at the packer which would limit the packer's ability to capitalize on export markets.

5) A highly contagious disease, African Swine Fever, has ravaged the Chinese swine industry. Before African Swine Fever broke in China in 2018, China produced over 4.5 million pigs annually, or approximately seven times U.S. production. The exact impact of this disease on the Chinese swine herd is still not apparent, but it is certainly devastating. As a result, the potential impact of marketing U.S. pork to China to fill the consumer demand is huge. China has recently banned ractopamine in imported pork as a trade measure.
6) Many U.S. packers have decided to only harvest pigs that are ractopamine-free in order to position their product for export to China, especially with progress being made in the current trade war. This is still a rapidly evolving situation, and packer requirements and markets may continue to change. Communication with potential markets is critical. Even different locations owned by the same packer entity may have different market requirements.
7) Therefore, this is a TRADE issue, not a food safety or swine health issue.

If pigs from a fair or exhibition will be sold directly from the show to a packer, show management should consider the following points when deciding whether to find new markets, ban ractopamine use, or changing to a non-terminal show and not selling pigs from the fair:

Option 1: Remain as a terminal or partially terminal show, do not ban ractopamine, find packer or alternative market that is ractopamine free

- Show management must find packer or alternative market interested in purchasing ractopamine-fed show pigs.
  This would likely be packers that are not selling to an export market. These may be difficult to find. If found, may have smaller capacity or be unable to harvest entire group. Markets may still change requirements as situation evolves. Market or packer could be farther away, increasing trucking cost and potentially increasing pig stress.
- May be a large price discount on pigs.
  Packers or other markets will most likely discount show pigs even more than past years, resulting in a very low market price to exhibitors. Show management may want to consider seeking other support for swine market projects, such as the possibility for subsidization of swine projects from donors, supporters or even the commercial industry which would have an interest in keeping the market show terminal from a biosecurity standpoint.
- In general, 4-H and FFA have enjoyed a "wholesome" image. Any positive tests, regardless of the substance, could tarnish that reputation. With this option, there is less concern of jeopardizing "wholesome" image of 4-H/FFA with a positive test and less likelihood of negative press or media.

Option 2: Do not ban Ractopamine, Non-terminal Show

- Serious biosecurity concern by commercial industry associated with comingling pigs from many sources and sending back home after show.
  Disease exposure to commercial industry a very large concern. Also, potential for exhibited pigs that are not necessarily ractopamine-free mixing with pigs that are ractopamine-free.
- Exhibitors would still need to find a (local) market after show.
  Local lockers and secondary markets may not be able to handle the large volume of an entire show, resulting in exhibitors having to take pigs home first and feed longer. This practice raises a potential biosecurity concern, and increases the feed expense associated with the project.

- Secondary markets may still have additional requirements, may not buy individual exhibitors and may discount pigs.
  - Less concern of jeopardizing "wholesome" image of 4-H/FFA with a positive test. Less likelihood of negative press.

Option 3: Ban Ractopamine, Terminal Show (or partially terminal)

- Show management must communicate with packer before making final decision. Will banning ractopamine use satisfy packer requirements and keep the market open?
- Must be able to enforce ban and rules.
  Is testing a good option? (see document by Karriker and Rademacher) How will the ban be enforced? Which animals will be tested? How many? How will those chosen for testing be identified? When will they be tested? Which test will be used? What are the logistics of getting testing completed? Who will incur the cost of testing? What are the ramifications of a positive test, to the exhibitor, the show or fair, future markets, and to the industry?
- Asking youth exhibitors to sign affidavit may not eliminate ractopamine use or cross-contamination. Show or fair must still enforce ban.
  Record keeping is a challenge – even for some adult producers. Is the affidavit legally binding? Will exhibitors be aware of and/or admit to ractopamine use?
- Cross-contamination concerns
  There are still ractopamine products in home barns, etc. Ractopamine appears to be easily cross-contaminated. Not all packers have banned ractopamine and some pigs may still be fed diets containing the feed additive. According to the FDA, ractopamine is still legal and effective and may be used in hogs not going to those markets that may be at the same show or in the same areas. There are similar products approved for use in beef cattle and turkeys, further complicating possible routes of cross-contamination, especially on fairgrounds, in show rings, etc. All aspects of feed manufacturing, feed hauling, feed storage, feed handling and feeder must be clean and free of ractopamine residue. A feed mill manufacturing diets with ractopamine for other swine, beef or poultry diets or is using meat and bone meal or fat from ractopamine-fed animals will not be able to meet the standard for "ractopamine free".
- What is the liability to the show, exhibitor and industry if a ractopamine-positive test occurs?
  Concern over losing packer access when/if a positive carcass is found. It was difficult for packers to accept show pigs even before this current situation. Shows might be forced to still find alternative market or change show rules if a positive carcass was found at a packer after the show had agreed to be ractopamine-free. There may be potential economic liability resulting from packer not being able to sell pork to export market. Who incurs the resulting loss of value? Once again, continual communication with packer is essential.
- Concern over a positive test(s) affecting the current "wholesome" image of 4-H and FFA
  Negative press associated with hogs testing positive and the potential for this situation to be misrepresented as food safety or animal welfare concern to consumers. Negative media involving the show pig industry has the potential impact of negative press for entire swine industry.

Ractopamine Free Pork and Implications for Use in Growing Pigs: Frequently Asked Questions

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In order to gain and preserve access to international markets that have banned the use of ractopamine in swine, several United States processors announced their intention to process only pigs that are free of ractopamine. There have not been recent changes to the regulatory status of ractopamine in the United States and processor approaches to eliminating ractopamine from their pig supply have varied. What follows represents an attempt to summarize the relevant scientific data about ractopamine in the pig, producer experiences and anecdotal information to guide producers adjusting to the new requirements. This document will be updated as new information is available. Specific references are available on request.

Q1: What is ractopamine, what does it do, and how long do the effects last?
A1: Ractopamine (Paylean®, Engain®) is a feed additive that changes how the pig partitions nutrients and energy to muscle and fat cells. It increases the amount of protein deposited in muscle cells and increases the rate that fat is removed from storage. The net effect is that a greater portion of the carcass is lean protein. The drug accomplishes this by activating a receptor on the surface of cells in the pig. Ractopamine is fed in the period immediately prior to marketing because these effects peak after a few weeks of continuous feeding and begin to subside. The changes to protein and fat deposition are not permanent and the rate of protein and fat deposition gradually returns to near baseline levels when ractopamine is no longer binding the cellular receptor. Although gradual, changes can be observed as quickly as seven days after removal of ractopamine from feed.

Q2: What is the difference between the United States Food and Drug Administration (FDA) "tolerance level" and being completely free of ractopamine?
A2: The FDA tolerance level is the level above which it is illegal to market a pig into the human food chain. This is a federal standard and applies to all pigs processed for consumption by humans. Pigs with levels above the tolerance are considered adulterated and cannot enter the food supply. The FDA tolerance level is based on an "acceptable daily intake" (ADI) by humans that would not cause any effects when consumed. This level is determined by scientific studies, includes a safety factor, and considers both average human body weight and average pork portion size of edible tissue. The resulting level in pork that allows consumption by humans and results in human levels below the ADI is the tolerance level in pork. Note that this does not consider non-edible tissues (such as urine or hair). In the case of ractopamine, the target tissues that were important to the determination of the tolerance level were pork liver and muscle. Additional studies demonstrated that nearly as soon as ractopamine treated pig food is removed, pork liver and muscle fall below these tolerance levels for human consumption. However, the edible tissues are not completely free of ractopamine and it is possible that non-edible tissues (such as urine and hair) have higher levels than liver or meat. When processors

require pigs to be completely free of ractopamine and test the pigs to confirm this, levels must be lower than the sensitivity of the test used in the tissue tested. While the FDA tolerance in muscle is 0.05 parts per **Million**, there are tests available that can detect ractopamine in swine tissues at 0.25 parts per **Billion**. There is approximately a 1000-fold difference between what is safe to market per the FDA tolerance and what can be detected in the pig by most tests including those that could be used by processors to verify that pigs they purchase are truly free of ractopamine.

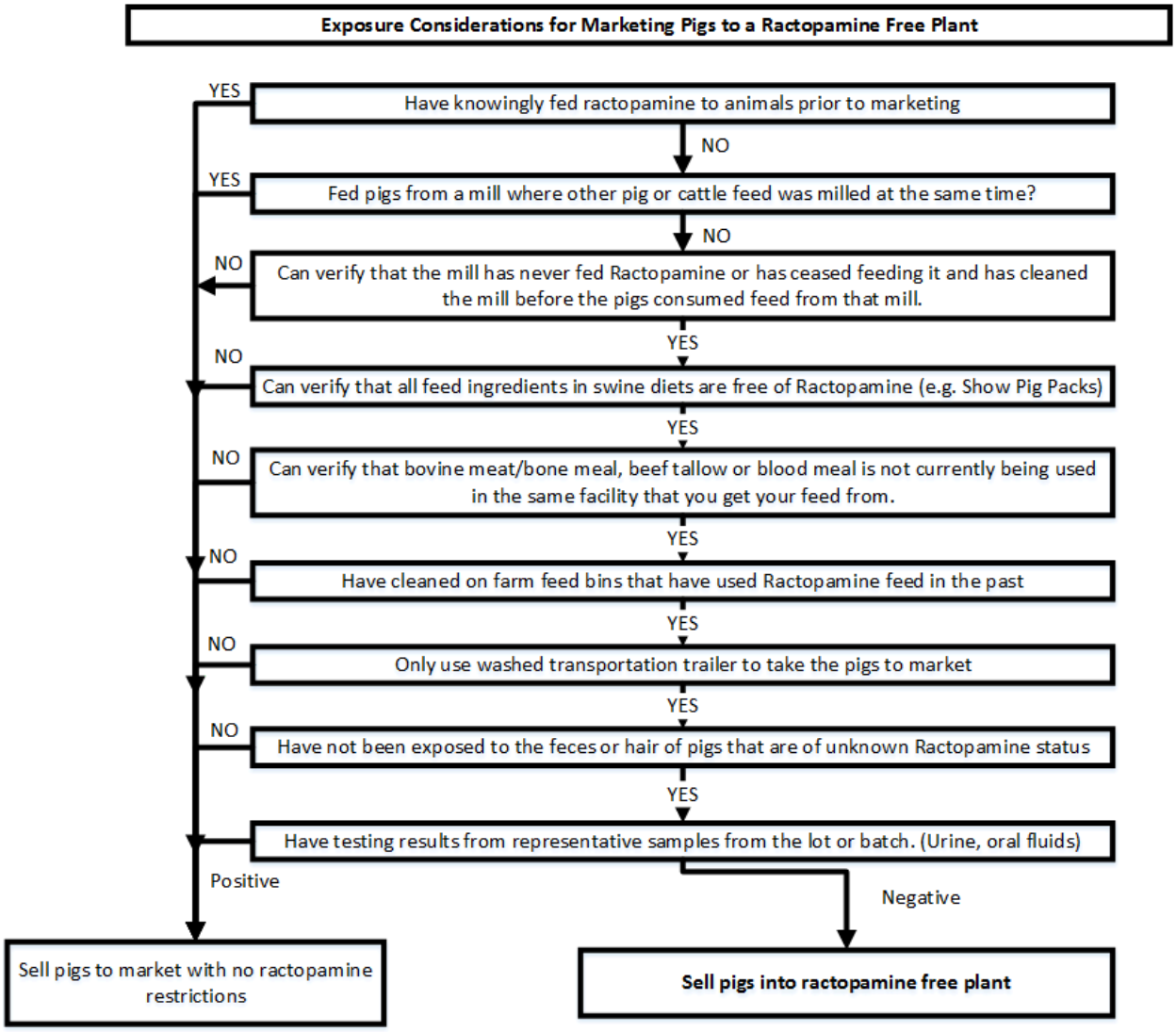
Q3: How much additional withdrawal time does it take to go from the FDA tolerance level (0.05 PPM) to a level that would test negative or free of ractopamine in most tests (0.25 PPB)?
A3: Unfortunately, there is not a study that directly measures this. At a minimum, ractopamine can be detected for 42 days after the end of feeding in pig hair. However, we do know that carcass changes induced by ractopamine are not permanent and begin to revert to the animal's baseline phenotype as soon as ractopamine is removed. So, it is likely that most or all benefit of feeding ractopamine would be lost by the time that the pig tested negative.

Q4: Given the extreme sensitivity of the tests available, can cross-contamination cause pigs that have never been fed feed treated with ractopamine to potentially test positive?
A4: There are a variety of reports that have identified cross-contamination between treated and untreated pigs as a likely problem. Contamination can happen directly through contaminated urine, feces, bedding and feed that untreated pigs have access to in pens or livestock trailers. Contamination has been anecdotally reported in swine and there are published examples in swine and other species. In one study, meat and bone meal was intentionally contaminated with 56 ppm of ractopamine and fed to pigs at a 7% inclusion rate. This led to pigs testing positive by urine testing. Further, in this study, one of the control diets was contaminated at the mill despite a plan for preventing ractopamine contamination. This was detected in the urine of pigs that were not fed the meat and bone meal and were part of the control group. A hospital based-prospective cohort study found that 8.1% of a human cohort of 370 patients tested positive for ractopamine in urine above a limit of detection of 0.026ppb. These levels were presumably obtained from the diet. Anecdotal reports from companies and feed mills that have eliminated ractopamine entirely indicate that detailed and repeated cleaning of all areas, even those that do not contact the feed directly, is necessary to achieve levels below current testing capabilities. Feed bins and feed lines on farms that have previously fed ractopamine must be cleaned as well to prevent contamination.

Q5: What happens if the processor finds a residue of ractopamine?
A5: If ractopamine levels are measured that exceed the FDA tolerance level by Food Safety and Inspection Service testing, FSIS will coordinate the appropriate follow-up, including notification to the Food and Drug Administration (FDA), AMS and FSIS District Enforcement Operations (DEO). FDA and FSIS/DEO will pursue regulatory action including criminal prosecution, where warranted. Each phase or ownership stage will independently have to demonstrate that their system requirements are adequate and are meeting standards. If the plant's own testing finds evidence of ractopamine, the plant will determine the response to the

owner or producer. The producer is encouraged to contact the plant of interest directly to understand requirements and implications of positive tests.

Q6: Do you have a checklist of steps that need to be considered to market my pigs to a ractopamine free harvest facility?
A6: The following flowchart will help guide considerations:



Q7: If I need my pigs to be ractopamine free, what do I need to do in terms of cleaning my feeding equipment/barn at home?
A7: Everything that has come in contact with ractopamine treated feed, pigs that were fed ractopamine (urine, feces, hair, etc) or dust from feed treated with ractopamine will need to be cleaned with soap and water. Pay special attention to:

- Discontinue getting feed from a feed mill that uses ractopamine, and discontinue its use at your farm at harvest. None of this feed should carry over to the next groups.
    - This would include any mill that feeds any ractopamine based products (Optaflexx® or Actogain® for cattle as well)

- Bulk bins, augers and feeders should be thoroughly washed for the next group of pigs. Clean up efforts may take months and repeated efforts to totally clean up.
- Be aware that bovine products in diet ingredients such as bovine meat, bone and blood meal, and tallow can be contaminated with ractopamine.
- Ractopamine is eliminated mostly via urine, but a significant portion is eliminated in the feces as well. This means that proper cleaning of pens, pits and anything in contact with these waste products is necessary to avoid exposure to subsequent pigs.
- There are anecdotal reports of pigs that were raised with ractopamine free feed testing positive at processing after transport in livestock trailers that previously hauled ractopamine fed pigs. Controlled research testing the parameters around how this might occur is not available.
- Although Ractopamine is at safe levels within 12 hours as per US regulations, it is near impossible to eliminate the residue to a level below detection by tandem mass spectrometry The entire operation or farm should be cleaned thoroughly to avoid contamination of waste, fluids, and even dust from previously Ractopamine fed pigs.

Q8: Do I need to talk to my feed mill where I am purchasing feed to ensure that they have steps in place to prevent potential residual?
A8: Yes! A clean feed mill with strong quality control to prevent contamination is a vital part of ensuring a ractopamine-free feeding program. Given the very low detectable levels of ractopamine in pork, cross contamination from feed is a significant potential issue if your mill also makes feed for other species using ractopamine. It may be a good idea to ask your feed mill if they stock ractopamine for other clients to gauge your level of potential cross contamination risk.

Q9: Will I be able to show pigs that have been treated with ractopamine at county and state fairs?
A9: At this time, county and state fairs are making decisions about allowing ractopamine in competition animals. It will likely depend on the ability of each terminal show to find a processor for the pigs and what that processor's expectations regarding ractopamine are currently. Not all processors in the United States have banned ractopamine at this time. Given the ease with which contamination of ractopamine free pigs can occur, shows may need to ban ractopamine completely to find a buyer that will purchase the pigs from the show.

Q10: Is there a test which would allow checking pigs at a county fair with results before pigs are shipped?
A10: There are a variety of validated tests including liquid chromatography–mass spectrometry (LC-MS), gas chromatography–mass spectrometry (GC-MS), lateral flow devices (LFD) and ELISA (ELISA) tests. Both LFD and ELISA tests can be deployed in the field at pen side in nearly real-time but GC-MS and LC-MS are laboratory-based tests. In total, there are at least 11 tests that are validated, the lower limit of detection ranges from 250ppb to 0.25ppb and these tests have been validated in feed, urine, tissue, and plasma. Testing has also been reported for hair using LC-MS, and the limited data on hair has found ractopamine for at least 42 days after the end of treatment. Since the study ended there, it is likely that hair would be positive longer.

These testing options range in cost from $250 - $675 per sample. You should consult with your veterinarian or diagnostic laboratory to establish which test is most appropriate for a specific situation.

Q11: What do we do with county fair pigs if packers refuse to purchase them because of ractopamine use?
A11: Fairs may consider banning ractopamine or marketing to a buyer that is not ractopamine free. Cross-contamination at several levels makes it unlikely that ractopamine exposed and ractopamine free animals could be housed and shown at the same fair and any marketed as ractopamine free.

Q12: Can packers or counties have parents/exhibitors sign an addendum to the drug residue statement saying pigs have never been fed ractopamine?
A12: Discussions about solutions for exhibit and competition pigs will have to involve a variety of stakeholders to develop a fair and practical system that allows all parties to be successful.

Q13: If liver is the marker tissue for FDA and FSIS compliance, is liver the tissue that will be used by processor driven testing to confirm that a pig has never ever been fed ractopamine?
A13: Processor testing to confirm that pigs are free of ractopamine may use a variety of tissue, fluid and test combinations based on that processor's objectives, resources and abilities. Liver is not a gold standard for zero tolerance. In the US, drugs that have a tolerance, as defined by the US FDA, also specify a tissue for the measurement of that tolerance since different tissues can have different levels of drug and require different times to eliminate a drug. For ractopamine, the United States FDA has established two tolerance levels and producers must be below both levels to comply. In swine, a tolerance of 0.15 ppm is established for liver, and 0.05 ppm for muscle. There are tests validated for these tissues as well as other tissues such as urine and plasma. If a US processor has established a zero tolerance for the pigs they buy, they may, or may not specify which tissue they are testing. A zero tolerance implies that all tissues would need to be free of the ractopamine. Specific processor protocols have included collecting bladders at processing and testing urine, plasma testing and oral fluids collection in lairage for testing prior to euthanasia. Other protocols are possible and are not standardized between all plants.

Q14: If an exhibitor buys pigs from a sale in March, that were fed ractopamine for a week before the sale, but exhibitor does NOT feed ractopamine the entire summer for the state fair in August, will the urine be negative, but tissue positive?
A14: The label for feeding ractopamine stipulates it is to be fed for the last 45 to 90 pounds of gain, meaning that feeding it to feeder pigs pre-sale (feeder pigs in March) likely illegal. No scientific studies have been published investigating the effects of ractopamine for the length of time between a potential March sale and August slaughter date. Therefore, we do not know for certain how long ractopamine could potentially be found in any tissue. It is found in hair at least as long as 42 days and would likely be found in these potential situations.

Q15: If an exhibitor hauls their pig that has NOT been fed ractopamine in the same trailer as their heifer that has been fed Optaflexx® (a cattle product containing ractopamine), can their pig test positive ractopamine?
A15: Unless the trailer is well cleaned, there is a risk of cross contamination that would be detected by current testing in a variety of tissues. Ractopamine is water soluble so thorough washing using soap and warm water should substantially reduce this risk. Both cattle and pigs excrete a portion of ractopamine as intact molecule that could then be consumed by another animal and potentially result in a positive test at the sensitivity levels of current tests. This has not been confirmed by direct measurement or scientific study at this time.

Q16: If an exhibitor is feeding ractopamine to pigs for a non-terminal youth show (summer type conference) where ractopamine is not banned, will the pigs in the same barn NOT being fed ractopamine have trouble at the state fair?
A16: While every situation is different, given the extremely low levels at which ractopamine can be detected in tissues and urine, cross contamination (even through feed dust) could possibly result in ractopamine positive animals that have never been directly fed ractopamine. This has not been confirmed by direct measurement or scientific study at this time.

Q17: If ractopamine is banned from use at a fair or exhibition with zero tolerance, and the standard test is urine (only champion and reserve have tissue samples taken), will urine be a clear way of eliminating competitors that use it?
A17: Urine testing will confidently identify pigs to which ractopamine has been fed. However, given the sensitivity of the testing available, it may also identify some animals that have been contaminated accidentally. It should be noted that either scenario (intentional use or contamination) is problematic for processors that are marketing pork to countries where it has been banned. There is likely a useful difference in concentration of ractopamine that would discriminate direct feeding (at least within a window that would provide competitive benefits) versus contamination of untreated animals. However, research is needed to determine what those levels might be or how reliably direct use could be distinguished from contamination.

Q18: If the manufacturers of swine ractopamine products withdraw them from the market in the near future, but ractopamine products are still FDA approved for swine, can producers substitute cattle products such as Optaflexx® for use in pigs?
A18: Products that are approved for use in feed may not be used in a manner that does not follow the label instructions. If a product is not labeled with instructions for feeding pigs, it cannot be legally used for pigs. If FDA approval is withdrawn, it will no longer be permissible to use even from stockpiled stores that were purchased prior to the date it is pulled from the market. There is no allowance for extra-label use of feeds containing ractopamine. The label must be followed exactly. This means that ractopamine that is only labeled for other species (such as Optaflexx® in cattle) cannot be legally fed to swine.

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