DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids and Aligning Other Regulations; Proposed Rule

Docket No. FDA-2021-N-0555

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

Economics Staff
Office of Economics and Analysis
Office of Policy, Legislation, and International Affairs
Office of the Commissioner

Table of Contents

I. Introduction and Summary

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). This proposed rule is an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the estimated one-time costs of this rule are small, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

This proposed rule if finalized would generate potential benefits in the form of cost savings for consumers with perceived mild to moderate hearing loss who wish to buy lower cost hearing aids not bundled with professional services and not requiring professional advice, fitting, adjustment, or maintenance but who are currently unable to buy such products online because of state regulations or because they do not shop online. We estimate consumer benefits of between $6 M (million) and $147 M per year based on fifth and ninety-fifth percentile Monte Carlo results with a mean of $63 M per year. Because this is an annual benefit, the annualized benefits are the same at 3 percent and 7 percent discount rates.

The proposed rule if finalized would also generate costs for hearing aid manufacturers for changing labeling of existing hearing aids as well as for reading the rule and revising internal standard operating procedures (SOPs) in response to the rule. We estimate one year costs of between $5 M and $15 M based on fifth and ninety-fifth percentile Monte Carlo results with a mean of $10 M, which corresponds to an annualized cost of between $1 M and $2 M with a mean of $1 M per year at both 3 percent and 7 percent discount rates.

Combining benefits and costs, we estimate annualized net benefits of between $5 M and $145 M per year based on the fifth and ninety-fifth Monte Carlo percentile results with a mean of $62 M per year at both 3 percent and 7 percent discount rate.

Table 1: Summary of Benefits, Costs and Distributional Effects of Proposed Rule

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year	$63	$6	$147	2020	7%	10 years	
		$63	$6	$147	2020	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative	Potential increase in hearing aid and hearing technology use leading to associated health benefits, potential fostering of innovation in hearing aid technology.						
Costs	Annualized Monetized $millions/year	$1	$1	$2	2020	7%	10 years	
		$1	$1	$2	2020	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative	Potential loss of consumer utility from inability to buy existing hearing aids under existing conditions						
Transfers	Federal Annualized Monetized $millions/year					7%		
						3%		
	From/ To	From:			To:			
	Other Annualized Monetized $millions/year					7%		
						3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: Small Business: Wages: Growth:							

II. Preliminary Economic Analysis of Impacts

A. Background

The current regulatory approach to hearing aids is based on the notion consumers generally require professional evaluation before they are sold hearing aids. Federal regulations allow, and all states currently have, state requirements governing the qualifications of those dispensing hearing aids, including in some cases bans or

restrictions on online sales. For these and other reasons, most hearing aids are currently sold through brick and mortar specialty retail outlets. Purchasing hearing aids through specialty retail outlets may increase the price of hearing aids by bundling the devices with professional services thus complicating comparison shopping and price competition, which are further complicated by the fact most specialty retail outlets carry only a limited selection of brands and models with many outlets carrying only one. When consumers are unable to easily cross-compare devices with different features (e.g., acoustic performance, battery life, mobile operating system compatibility), it may impair the discovery function of determining what features they would like out of their device. Complications relating to comparison shopping may thus decrease consumers' satisfaction with their hearing aids. Current regulations may also play a role in terms of concentration in the hearing aid industry in which six larger manufacturers produced about 98 percent of hearing aids in 2013, Ref. [1]. Increased industry concentration may be associated with increased opportunities for non-competitive pricing.

Hearing aids sold online are not subject to these effects and are currently available in most states. Generally similar sound amplification products known as personal sound amplification products (PSAPs) are also not subject to this effect and are also currently available in all states both online and in brick and mortar general retail outlets. PSAPs are intended to amplify sound in specific listening environments for non-hearing impaired consumers and are not intended to aid a person with or compensate for impaired hearing. Although PSAPs share many characteristics with hearing aids, they are not classified as hearing aids for regulatory purposes and are marketed differently from hearing aids.

While there is an online market for hearing aids that are not bundled with professional services, online sales are restricted in some states, and not all consumers are able or willing to purchase hearing aids online. Enabling the sale of hearing aids without bundled services in brick and mortar retail outlets will result in a new relatively low cost option to buy for FDA-approved hearing aids. Thus, the size of the market for FDA-approved hearing aids, and the overall number of individuals who will benefit from access to hearing loss technology, will likely increase at least to some extent as a result of the rule.

B. Market Failure Requiring Federal Regulatory Action

Our regulations allowing the preempted state regulations may be viewed as part of the overall government response to an ostensible market failure we addressed previously and have now reassessed. We have tentatively determined hearing aid technology has improved sufficiently that some hearing aids can now be made safe and effective without professional evaluation or involvement. Therefore, we propose to define and establish requirements for a category of hearing aids that can be sold over the counter (OTC), and such requirements will preempt certain state regulations, such as those requiring that hearing aids be sold by licensed hearing aid dispensers.

To the extent current regulations facilitate concentration in the hearing aid industry by setting up conditions of sale amenable to any given state licensed hearing aid dispenser tending to dispense only a small number of brands, and in some cases only one brand, this rule may also address the market failure of "market power," OMB Circular

A-4 defines "market power" as occurring when firms "reduce output below what would be offered in a competitive industry in order to obtain higher prices." We do not have information suggesting the large manufacturers dominating the hearing aid industry exhibit market power defined in this way or fail to price their products competitively; however, such market power is always a concern in any highly concentrated industry.

C. Purpose of the Proposed Rule

The proposed rule would define and establish requirements for a new regulatory category for OTC hearing aids, including new labeling requirements for OTC hearing aids, and make corresponding changes to the existing regulatory framework, including defining hearing aids not meeting the proposed OTC requirements as prescription medical devices, and amending the existing labeling requirements which would apply to prescription hearing aids.

D. Baseline Conditions

Costs and benefits must be assessed relative to a baseline. In this analysis we use the existing state of affairs under the current regulatory regime as the baseline.

E. Benefits of the Proposed Rule

This rule would define and establish requirements for a new regulatory category, OTC hearing aids, and change the regulatory status of existing hearing aids not currently

prescription medical devices and not meeting the proposed requirements for OTC hearing aids to prescription medical devices. Defining a new category for regulatory purposes does not automatically or necessarily generate social benefits but does create the potential for benefits or costs to occur.

One potential benefit of this rule is that some consumers with mild to moderate hearing loss who buy hearing aids through brick and mortar specialty retail outlets under the baseline scenario may be able to obtain their hearing aids more cheaply and thus experience cost savings for two reasons: 1) the product will be available without the bundling with professional services generally included with hearing aids bought through brick and mortar specialty retail outlets from state licensed distributors, 2) the actual device hardware and software may become cheaper particularly over time due to a potential increase in price competition and reduction in barriers to entry, which may spur product innovation and development. These cost savings may involve out of pocket expenditures for consumers who buy their own hearing aids, reductions in insurance premiums for all members of insurance plans that cover hearing aids, or potential reductions in taxes for all taxpayers given the reductions in Medicaid costs. For consumers obtaining hearing aids through insurance plans that cover hearing aids, the cost savings will accrue to those consumers, other consumers in those insurance plans, and those insurance companies through reduced costs for hearing aids. For consumers buying hearing aids not in insurance plans that cover hearing aids, the cost savings will accurse to the consumers buying the hearing aids. For consumers obtaining hearing aids through Medicaid, where that option is available, the cost savings will accrue to taxpayers funding the Medicaid program.

Another potential benefit of this rule is we anticipate that the introduction of OTC hearing aids will expand access for consumers who have mild to moderate hearing loss yet do not currently use hearing aids and would not have begun using hearing aids under the current rules. OTC hearing aids will likely be less expensive than those sold as a bundle with professional services and will be sold in brick and mortar stores. It is likely that there are consumers who prefer to purchase hearing aids in brick and mortar stores, or who don't have access to the online market, but whose budgets do not allow them to afford the current bundled product even though they may place a high value the benefits hearing aids would provide. These consumers also may not buy PSAPs because they are not labeled as hearing aids and do not meet FDA regulations, because PSAPs are intended to amplify environmental sound for non-hearing impaired consumers. The number of these consumers who currently lack hearing aids who will obtain them OTC will depend on the elasticity of demand relating to the price differential between models currently sold in specialty retail bundled with professional services and the probably although not necessarily cheaper models with less advance technical features sold unbundled with professional services of the sort current available online. We do not have information on the relevant elasticity and therefore cannot estimate the number of consumers who would benefit from expanded access. We request comments on potential changes in hearing aid use, hearing technology in general use, and the health benefits from increased use of hearing technology that may result from relatively low-cost OTC hearing aids becoming available in general retail stores. An increase in the uptake of hearing aids specifically resulting from the availability of OTC hearing aids, if it were to occur, would generate various benefits including the potentially important but difficult-

to-monetize benefit of inclusion of those with hearing loss into family, social, economic, civic, and religious life, and the reduction of stigma around hearing aid use (such that hearing aids would become more akin to eyeglasses). More serious health consequences including dementia and ER visits may be associated with hearing loss, albeit perhaps not typically at the level of mild to moderate hearing loss relevant to this rule, although one's response to mild or moderate hearing loss may have implications for one's response to later and more advanced hearing loss.

Some consumers whose current hearing aids do not meet the proposed technical requirements for OTC hearing aids and who choose to switch to OTC devices may lose some features of their existing hearing aids and thus experience negative benefits albeit reduced by a countervailing reduction in cost. For this reason, we cannot infer a net increase in consumer welfare relative to the baseline from consumers switching to OTC hearing aids because these consumers would not have the choice of maintaining their current hearing aids under current conditions. However, we can infer that if these consumers experience a net loss in welfare, any net loss must be smaller than the net loss that would result from continuing to use their current devices as prescription medical devices because otherwise they would not switch to the OTC devices.

Other benefits may ensue from the ability of consumers to easily compare OTC devices with different features (e.g., acoustic performance, battery life, mobile operating system compatibility). These benefits may include improvement in the discovery function of determining what features consumers would like out of their devices. Facilitating comparison shopping of hearing aids by offering an OTC option may thus increase consumers' satisfaction with their hearing aids in the long term.

The rule reduces the barriers to entry for producers into the brick and mortar retail segment of the hearing aid market. In addition to these potential new entrants, it is possible that expansions in market size resulting from hearing aids being available in brick and mortar general retail outlets (and corresponding marketing efforts) will create new incentives for firms to engage in technological innovation that enhances product quality or reduces the costs of production. Innovation in product features of hearing aids could increase the array of products offered to consumers and improve consumer welfare if the quality of the devices improves relative to prices. This innovation may take the form of entirely new entrants, but it also may incentivize existing PSAP providers to improve their technology to meet FDA standards and/or incentivize existing online providers to reach additional customers in brick-and-mortar stores—any of which could increase consumers' options and ability to access devices of sufficient quality to meet FDA standards for addressing mild-to-moderate hearing impairment. We request comments on the innovation in hearing aid technology that could result from a larger consumer base of potential hearing aid users.

1. Consumer Cost Savings and Benefits to New Users

The closest existing analog to the proposed OTC hearing aids are relatively low-cost hearing aids sold online bundled with minimal or no professional services. However, some states currently do not allow or heavily restrict online sales of hearing aids. The main source of potential negative costs or cost savings for this proposed rule is that, if

finalized, the sort of relatively inexpensive hearing aid currently sold online in most states will become available in all states and also in brick and mortar general retail outlets rather than online only. This may result in some people who currently buy hearing aids through specialty retail bunded with professional services or would have bought such hearing aids even in the absence of this rule, to switch to OTC hearing aids. It may also result in some people who do not currently buy hearing aids and would not have begun buying hearing aids in the absence of this rule to begin buying OTC hearing aids. We tentatively suppose the share of the market of such devices will be along the lines of similar products sold online, after correcting for the unavailability or restricted status of online sales in some states, the potential inability or unwillingness of some consumers to buy such devices online, and other features that may distinguish online products and OTC devices sold in brick and mortar stores, such as potentially increased product visibility, opportunities for impulse buying, etc. However, we have insufficient information to determine the degree to which that market share will be generated by current users switching to OTC hearing aids or new users taking up OTC hearing aids. Because of the uncertainty associated with predicting the uptake of hearing aids and valuing benefits for new users we discuss both possibilities separately then consider a mix of the two.

In 2008, the last year for which we were able to find data, about 4.7 percent of hearing aid sales involved relatively low-cost models bundled with little or no professional services purchased online. Ref. [2]. The data are old and such products may represent a greater share of the hearing aid market today. Our benefit estimates, based ultimately on the market share of such products, will be low to the extent this percentage has increased since 2008. We request information relating to the current percentage of

hearing aids sales involving such products. However, the total upon which this percentage is based includes hearing aid sales in three states that do not currently allow online sales and may not have allowed online sales in 2008: Florida, New York, and West Virginia. If we use the general populations of the states involved to correct for this effect, then the percentage of hearing aids sold online in states allowing such sales would be about 5.4 percent. If we apply a similar correction for the ten states that place non-trivial restrictions on online sales (California, Illinois, Kansas, Massachusetts, Missouri, Nevada, New Hampshire, Oregon, Texas, and Washington), then the percentage of hearing aids sold online in states that allow such sales with no or only trivial restrictions would be about 9.0 percent. However, the effects of regulatory restrictions that stop short of a ban are unclear and may vary from operating similarly to a ban to having little or no effect on online sales. If we use a uniform distribution and treat these regulations as approximating a ban at one endpoint and having no effect at the other endpoint, the mean of the estimated percentage of hearing aids sales composed of relatively low-cost models purchased online would be about 7.2 percent. This increase in the percentage of hearing aid sales composed of relatively low-cost models not bundled with professional services due to effective circumvention of state laws restricting such products sold online is one element of the potential benefits generated by this rule.

Another element of the potential benefits generated by this rule is that the relatively low-cost hearing aids currently sold online may become available in brick and mortar general retail outlets and hence to consumers who choose not to shop online. A nationally representative survey of adults from 2016 showed about 79 percent of Americans made an online purchase of any type. Ref. [3]. The data are a few years old

and do not relate specifically to hearing aids or the population buying hearing aids for mild to moderate hearing loss. We request information providing better estimates of the degree to which the relevant population would find buying a hearing aid online acceptable but buying a similar product in a brick and mortar store acceptable. If we use the population that shopped online to correct for this effect, then the effective market share going to lower cost hearing aids of the sort currently sold online would increase further to about 9.1 percent. These adjustments, in total, represent an increase of 4.4 percentage points over the current rate of 4.7 percent.

Based on survey data from 2015, about 3.2 percent of the adult (18 years or older) population of the US owned a hearing aid. This implies about 9.6 million adults owned hearing aids. However, about 3 percent of those who reported owning hearing aids reported not using them. This implies about 9.3 million adults reported both owning and using hearing aids in 2015. About 60 percent of hearing aid owners in 2009 reported having mild or moderate hearing loss of the sort relevant to OTC hearing aids. This suggests about 5.8 million consumers currently own and use hearing aids to address mild to moderate hearing loss. In the 2015 survey data, about 74 percent of respondents reporting hearing loss reported hearing loss in both ears (bilateral hearing loss). This suggests about 4.3 million consumers with mild to moderate hearing loss who own and use hearing aids own two hearing aids each and 1.5 million consumers with mild to moderate hearing loss who own and use hearing aids own one hearing aid each. This suggests there are about 10 million hearing aids currently being used to treat mild to moderate hearing loss in the US.

One hearing aid provider suggested the average lifespan of current hearing aids is about 4 to 6 years, which we represented using a uniform distribution running from 4 to 6 years with a mean of 5 years. Ref. [4]. This implies about 2 million existing hearing aids need to be replaced each year. In that case a shift of 4.4 percentage points toward relatively low-cost OTC hearing aids sold in stores or online would represent about 88,210 hearing aids.

The cheapest hearing aid we found online at the time we wrote this analysis , was $399 or $411 in 2020 dollars. The average cost of an economy-level hearing aid bundled with professional services purchased from a specialty retail outlet in 2014 was $1,657 or $1,849 in 2020 dollars. Ref. [5]. Given our assumption that OTC hearing aids are likely to be similar to relatively lower cost models current sold online, consumers most likely to switch to OTC hearing aids from hearing aids bought in specialty retail outlets are probably currently using economy-level hearing aids. If this price difference is similar to the future price difference between OTC hearing aids and economy-level hearing aids currently sold through special retail outlets, these data and assumptions suggest possible cost savings on the order of $1,438 per unit, which would amount to a total cost savings of about $127 million per year. The savings would be higher if prices of OTC hearing aids are pushed lower than comparable models currently sold online, perhaps due to the absence of restrictions on online sales in some states.

However, we do not know how much of this cost savings would represent a net increase in welfare for consumers because consumers moving from relatively higher-cost products sold in specialty retail outlets to relatively lower-cost products sold OTC would give up bundled professional services and may give up some product features as well and

hence may experience negative non-monetary benefits. For some consumers who choose to switch to OTC hearing aids, the net value of the cost savings may be only slightly higher than the associated decrease in non-monetary benefits from the loss of professional services and product features. Indeed, some consumers may elect to pay for professional services even though they choose to buy OTC hearing aids thus negating a major element of the potential cost saving. For other consumers the net value of the cost savings may be much higher than any associated decrease in non-monetary benefits because they do not value the foregone professional services or product features. Similarly, some consumers who switch from products sold in specialty retail bundled with professional services may only value those services when they first decide to buy hearing aids, perhaps to confirm a need for hearing aids or the level of hearing loss, and later do not value professional services related to adjusting or using particular devices, keeping abreast of technological developments, or monitoring changes in their own hearing. To reflect this uncertainty, we use a uniform distribution running from 0 to represent a very small increase in welfare from the cost savings to the full value of the cost savings. The mean of that distribution is about $63 million per year.

Another possibility is that the market share of OTC hearing aids may involve only or significant numbers of new users who would not have bought hearing aids otherwise.

For new users the associated benefit would be the net gain or utility from taking up hearing aids. Assuming the amount consumers would be willing to pay for hearing aids is based on their subjective assessment of the potential benefits to be gained from using hearing aids, including the positive utility from beneficial health effects and the negative utility or disutility from negative effects like inconvenience, stigma effects, and

so on, we can infer the perceived net utility gains for consumers who will not buy a currently available economy-level hearing aid bundled with professional services purchased from a specialty retail outlet for $1,848, but who would buy an OTC hearing aid at an estimated cost of $411, would be between $411 and $1,848, which under a uniform probability distribution gives a mean of $1,130. Assuming consumers have realistic expectations regarding product life and plan on replacing the device in 4 to 6 years with a mean of 5 years, the estimate of annual perceived net benefits including health benefits for new users of hearing aids would be between $0 and $288 with a mean of $144. If we apply this figure to the estimated number of new hearing aids required to generate the anticipated market share going to these devices we calculated in the context of potential cost savings for existing users, we obtain estimated annual benefits of between $0 and $27 M per year with a mean of $14 M per year. This is substantially below the estimate we obtained when we assumed generating the anticipated market share would involve only existing users switching to OTC devices. If the relevant market were generated by some combination of existing users switching to OTC hearing aids and new users, the mean estimate of benefits would lie in a range between $14 M per year and $63 M per year with a mean of those means of about $39 M per year.

However, there are alternative methods of valuing the health benefits of hearing aids for new users in particular that provide significantly different results and, in particular, the potential for much higher estimates of net benefits. See the appendix for one such approach. To the extent these methods are meant to be based on the subjective value of the benefits of hearing aids by prospective new users, they are difficult to reconcile with observed market behavior. However, there may be ways the reconcile the

estimates using independent estimates of the disutility associated with hearing aids, both in terms of stigma effects and practical issues related to use and maintenance, and considering that perceived health benefits from the uptake of OTC hearing aids would be incremental from any benefits currently available through other hearing technology such as PSAPs, although some consumers may not be familiar with PSAPs and may not consider them potential substitutes for hearing aids.

However, it should be noted the uptake of hearing aids is a complex issue and the effect of the introduction of OTC hearing aids on the overall use of hearing aids is unclear. In the US, as in other countries, the prevalence of hearing aid use is significantly lower than the prevalence of hearing loss. One study from 2012 estimated an overall utilization rate for hearing aids of about 14 percent. A study from 2011 found a strong relationship between hearing aid use and the severity of hearing loss, with 3 percent of those with a mild loss, 40 percent of those with a moderate loss, and 77 percent of those with a severe loss regularly wearing hearing aids. In that study, the severity of hearing loss, college education, and leisure noise exposure were positively associated with hearing aid use, but race / ethnicity, age, sex, and income were not significantly associated with the use of a hearing aid. A study from 2014 found utilization rates of 4 percent of those with mild hearing loss and 23 percent for those with moderate to severe hearing loss. Another study from 2014 found individuals with the highest income were more likely to use hearing aids than individual with the lowest income; however, that study did not adjust for education. A study from 1998 found an overall utilization rate of 15 percent and a utilization rate of 33 percent for participants who reported significant communication problem and handicaps. Factors associated with hearing aid use in that

study were severity of hearing loss, age, education, performance on word recognition tests, and self-reported hearing loss. Some potential reasons for low usage rates may be that some consumers with mild to moderate hearing loss don't realize they have measurable hearing loss, don't believe hearing aids would be beneficial for them, or don't believe the benefits would be worth the costs.

Because of the uncertainties associated with estimating uptake of hearing aids due solely to changes in price and availability, given concomitant changes in bundling with professional services as well as potential changes in product characteristics, we have based our benefits estimate on the assumption the primary factor in generating the estimated market share will be existing users of hearing aids switching to OTC devices in markets where they are currently unavailable. We request information relating to that assumption relative to the significance of new users and also to the most appropriate methods for valuing net benefits of hearing aids to new users.

F. Costs of the Proposed Rule

Defining a new category for regulatory purposes does not generate social costs; no one will be required to develop or offer for sale OTC hearing aids and no one will be required to buy them. However, changing the status of existing hearing aids to prescription medical devices may generate social costs relative to the baseline.

For manufacturers of hearing aids currently on the market, the least costly way to comply with the rule depends on whether the existing hearing aid meets the proposed technical specifications, performance limits, and design requirements for OTC hearing

aids. If so, the least costly option is likely to revise the product labeling to make it consistent with the proposed OTC hearing aid labeling requirements and sell the device as an OTC hearing aid under the proposed conditions for sale. If the device does not meet the proposed technical specifications, performance limits, and design requirements for OTC hearing aids the least costly option is likely to accept the definition of the device as a prescription medical device, revise the product labeling to make it consistent with the proposed prescription hearing aid labeling requirements, and comply with state regulations relating to prescription medical devices. We tentatively assume hearing aids currently sold online are the most likely to be consistent with OTC technical specifications, performance limits, and design requirements and require only a labeling change while hearing aids currently sold through specialty retail outlets will more likely convert to prescription medical devices. In either case manufacturers would also need to read and understand the rule and revise internal SOPs in response to the rule.

We do not expect changing the regulatory status of some hearing aids currently on the market to generate costs for consumers. Based on current practices relating to the sales of hearing aids, we do not expect consumers whose current hearing aids do not meet the technical requirements for OTC hearing aids who wish to continue using those devices as prescription medical devices will see additional costs. We anticipate they will be able to follow current procedures for obtaining their hearing aids and do not anticipate increases in product prices due to additional state regulations and restrictions on prescription medical devices. We request information on potential consumer costs associated with existing devices becoming classified as prescription medical devices.

1. Relabeling

The rule will require all current hearing aids to be relabeled according to either the proposed OTC or prescription hearing aid labeling requirements. About 105 firms manufacture air conduction hearing aids of the type that may be affected by this rule. Casual online research indicates one large manufacturer is currently offering 15 models each of which would require new labeling. Smaller manufacturers may offer fewer models. If we estimate the number of products per manufacturer using a uniform distribution running from 1 to 15 with a mean of 8, we get a mean estimate of 840 products requiring relabeling. Based on a compliance date 240 days after publication of a final rule based on this proposed rule (an effective date of 60 days after publication plus a compliance period of 180 days after the effective date), our 2015 labeling cost model suggests a one-time mean cost estimate for relabeling of about $6 M. Ref. [6] We based our estimate of label change costs on the mean costs for a major label change plus the mean cost of an insert label change plus the cost for lost label inventory. We used the cost estimates for a major label changed based on the description of a major label change in the model documentation. For printing process for the major label change and insert, we used a weighted average of the different printing methods listed based on the overall distribution of labels produced using the different methods in the model documentation. We estimated inventory loss using the model tab on inventory costs suggesting no loss of package inventory and ten percent loss of existing insert inventory.

2. Reading and Understanding the Rule

Any new regulation must be read and understood by those affected by that regulation. Using the same labor times and classifications we have used in previous analyses, we assume this may require 5 hours of time for one each of the following three types of personnel: executive, lawyer, and marketing manager. The time estimate is based on an average reading speed of 200 to 250 words per minute and document length of approximately 32,000 words for a reading time of approximately 2.5 hours, plus a comparable time to consider material. Using recent BLS wage rates and doubling for employee benefits and overhead, we estimate this one-time cost at about $0.3 M. Ref. [7]

3. Revising Guidelines or Standard Operating Procedures

In addition to the activity required by this rule, manufacturers would need to revise internal guidelines or standard operating procedures (SOPs) to reflect those requirements. Using the same labor times and classifications we have used in previous analyses, we assume this may require 10 to 25 hours of time for one executive, 40 to 100 hours for one marketing manager, and 80 to 150 hours for one technical writer. These time estimates are based on estimates we used for the cost of revising standard operating procedures for an unrelated issue involving direct-to-consumer prescription drug advertisements, which were accepted without public comment in the analysis of that proposed rule and increased at the high end by 25 percent during the analysis of the corresponding final rule stage. These costs are meant to be rough estimates. We do not have sufficient information to fine tune the cost of revising guidelines or SOPs in

particular cases. We request information on the cost of revising guidelines or SOPs in this instance. Using recent BLS wage rates, we estimate this one-time cost at $4 M. Ref. [7]

4. Costs Associated with State Regulation of Prescription Medical Devices

Currently, states regulate the personnel who may distribute hearing aids. We have no reason to suppose states will impose more onerous restrictions on hearing aids that will be prescription medical devices than currently. However, it is possible changes in state regulation of prescription hearing aids as well as potentially increased variation in state regulation of prescription hearing aids may increase the cost of hearing aids that convert to prescription medical devices. Although this rule would not cause the state actions that would generate these costs, it would generate the potential for such costs to occur.

5. Summary

We used Monte Carlo analysis to estimate annualized net costs of between $1 million and $2 million per year based on the fifth and ninety-fifth Monte Carlo percentile results with a mean of $1 million per year at both a discount rate of 3 percent and 7 percent.

Table 2 – Summary of Costs, Monte Carlo Run Means and Percentiles, Millions

	Mean	5% Percentile	95% Percentile
Costs in First Year Only			
Label Changes	$6	$1	$12
Revise SOPs	$4	$3	$5
Read Rule	$0.1	$0.1	$0.2
Total Costs			
Total Cost Year 1	$10	$5	$15
Total Cost Year 2 and After	$0	$0	$0
Annualized Costs			
Annualized Cost Over 10 years Infinity at 3 %	$1	$1	$2
Annualized Cost Over 10 years Infinity at 7 %	$1	$1	$2

G. Distributional Effects

The primary actors likely to gain from this rule are brick and mortar general retail outlets that may begin selling OTC hearing aids, manufacturers who may supply OTC hearing aids to retail markets but may not have a network of affiliated specialty retail outlets, including new entrants to the hearing aid industry as well as current producers of PSAPs and online hearing aids, and consumers with mild or moderate hearing loss who currently use hearing aids or would have begun using hearing aids even in the absence of this rule but do not value the professional services typically bundled with hearing aids when purchased through specialty retail outlets or the features of hearing aids sold through specialty retail outlets in states that currently disallow or restrict online sales of hearing aids or in any state in the case of consumers who simply choose to not purchase such products online but would purchase the same sort of product in brick and mortar stores. Consumers most likely to fit into this category are lower income consumers who

live in rural areas remote from specialty hearing aid retailers and general retailers selling related PSAPs, consumer with poor internet connectivity, and less educated consumers who have difficulty with online shopping where it is available. Thus, this proposed rule, if promulgated, would benefit communities that would conventionally be classified as disadvantaged, vulnerable, or marginalized communities. We request information related to potential hearing aid users who find accessing specialty hearing aid retailers difficult, who cannot or will not shop for hearing aids online but will buy comparable products in general retail, who do not consider other forms of hearing technology such as PSAPS sold in general retail close substitutes for hearing aids.

The primary actors likely to lose from this rule are hearing health care professionals and specialists who currently dispense hearing aids through specialty retail outlets in states that currently disallow or restrict online sales of hearing aids who may lose some of their current customers to the OTC hearing aid market in the same way they may have previously lost customers to online sales and PSAPs, and established hearing aid manufacturers that may lose some of their consumers to new entrants selling OTC devices in states that currently disallow or restrict online sales of hearing aids. Thus, this proposed rule, if promulgated, would not inappropriately burden communities that would conventionally be classified as disadvantaged, vulnerable, or marginalized communities. A possible exception would be that some people in communities that might conventionally be classified as disadvantaged, vulnerable, or marginalized who prefer buying hearing aids bundled with professional services sold in specialty retail may be made worse off when OTC products are introduced as competing products, for example,

if they live in a remote small town and work with an audiologist who is currently able (but just barely) to stay in business and who finds it advantageous after the introduction of OTC hearing aids to move to a larger urban area. We do not have sufficient information to predict the severity of these distributive effects and request comments on the potential distributive impacts of this rule.

H. International Effects

Many hearing aid manufacturers, including five of the six large companies that currently dominate the world-wide market for hearing aids, are based outside the US. These firms would accrue the relatively modest cost associated with relabeling existing hearing aids and may face increased competition from entrants into the OTC haring aid market.

I. Uncertainty and Sensitivity Analysis

The primary source of uncertainty for both benefits and costs is the number of consumers switching to OTC hearing aids. We assumed modest changes in behavior based on current consumption patterns relating to online hearing aid sales, the general shopping patterns relating to online versus brick and mortar outlets, as well as the general availability of PSAPs. However, it is possible OTC hearing aids may be or become substantially more attractive to consumers than hearing aids currently offered online and PSAPs, either because they vary in some relevant way such as product characteristics or cost or in the case of hearing aids sold online because simply appearing in brick and

mortar general retail outlets makes them dramatically more visible or acceptable to consumers than comparable models sold online. If more consumers convert to OTC hearing aids than anticipated, more consumers will obtain the potential cost savings and fewer consumers will need to arrange additional visits to licensed providers and potentially pay more for hearing aids that convert to prescription medical devices.

An important source of uncertainty for cost savings is the eventual price of OTC hearing aids. Sound amplification technology can range in price from under one hundred dollars for some PSAPs to relatively low-cost hearing aids available online for several hundred dollars to relatively expensive hearing aids with many advanced features sold through specialty retail outlets for a few thousand dollars. We assume OTC hearing aids at least initially may have similar costs and features to hearing aids currently available online. However, if they are much simpler devices and priced even lower, perhaps more similar to PSAPs, the potential cost savings for consumers who choose to use them would be greater than anticipated, although of course the change in product capabilities and characteristics and thus the potential decline in utility from switching to OTC hearing aids from current hearing aids may also be greater than anticipated.

Another important source of uncertainty for costs is the percentage of consumers with mild to moderate hearing loss who own and use hearing aids who would need to make additional visits to licensed providers if they wish to obtain prescriptions for hearing aids that convert to prescription medical devices. We assumed those aged 70 and over would have no additional cost but those under age 70 would have a 0 to 100 percent probability of needing to make an additional visit to a licensed provider to obtain a prescription. If most of these consumers can obtain prescriptions for hearing aids without

scheduling additional visits to licensed providers, the costs associated with existing devices converting to prescription medical devices would be lower than anticipated.

With respect to the discussion of potential new users, the main sources of uncertainty are the numbers of new users and the value of the hearing aids to new users. As with existing users, if OTC hearing aids represent a bigger departure from the current situation, including online hearing aids and PSAPs, then the number of new users may be higher than estimated.

J. Analysis of Regulatory Alternatives to the Proposed Rule

1. Extend Compliance Date

Another alternative would be to extend the compliance date by delaying the effective date or extending the compliance period. Extending the compliance date of any rule requiring products to be relabeled or repackaged reduces costs by allowing firms additional time to dispose of existing labeling and package inventory. In this case the labeling costs are a relatively minor component of total costs. If we extend the compliance date from 240 days after publication to 365 days after publication, our labeling cost model suggests we could increase the percentages of required labeling changes coinciding with regularly scheduled labeling changes from 2 percent to about 4 percent, although it would not change the estimated 10 percent of paper inserts or 0 percent of packaging lost. This would reduce the one-time labeling costs by about $0.1

M. However, it would also delay consumer benefits by an additional four months, which based on estimated annual cost savings would imply a reduction in cost savings in the first year of about $16 M.

2. Propose Fewer or Less Restrictive Specifications and Requirements for OTC Hearing Aids

A third alternative would be to revise the proposed specifications and requirements for OTC hearing aids to further reduce the cost of those devices. For example, we could look at the specifications that may generate differences in costs relative to low cost PSAPs and revise those with the intent of encourage OTC devise more similar to PSAPs than existing hearings aids sold online. We do not have enough information on the likely effect on benefits and costs of revising these specifications and requirements to allow us to evaluate these types of changes. We request information on the potential costs and benefits of revising the proposed specifications and requirements relating to OTC hearing aids.

III. Initial Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. We believe we can certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. The estimated annualized cost over ten years is $0.009 M per firm, which is unlikely to represent more than three percent to five percent of the revenue

of an affected manufacturer. However, we note that some uncertainty exists as to these impacts, so we have chosen to draft a compliant IRFA. We request comments relating to the effect of this rule on small manufacturers. This analysis, as well as other sections in this document, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

A. Description and Number of Affected Small Entities

FDA Medical Device Registration data shows 105 firms manufacture air conduction hearing aids sold in the US in 2015. Hearing aid manufacturing appears in North American Industry Classification System (NAICS) code 334510, Electromedical and Electrotherapeutic Apparatus Manufacturing. The Small Business Administration definition of a small business in this NAICS code is a firm with 1,250 or fewer employees. According to this definition, 100 hearing aid manufacturers are small businesses.

In the PRIA, we also discussed potential distributional effects that may result from this rule, including a potential reduction in business for specialty retailers selling hearing aids bundled with professional services and a corresponding increase in business for general retailers selling OTC hearing aids, any of which may be small businesses, we do not consider these market effects following from voluntary consumer and market behavior in response to new opportunities to correspond to the effects relevant to this section. Doing so would imply an objective of preserving the market share of existing firms from potential changes generated by consumer and supplier behavior, which would

be inconsistent with neutrality toward firms, including small firms, that may gain or lose revenue from such changes and potential entrants.

B. Description of the Potential Impacts of the Rule on Small Entities

In the preliminary economic analysis for this proposed rule, we estimated mean one-time costs for hearing aid manufacturers of about $10 M (fifth percentile $4 M, ninety fifth percentile $15 M), or about $0.09 M per firm. Annualized over ten years the mean annual cost would amount to $1 M, or about $0.009 M per firm.

C. Alternatives to Minimize the Burden on Small Entities

In the preliminary economic analysis for this proposed rule, we discussed an alternative that would reduce expected costs for small entities.

1. Extend Compliance Date

If we extend the compliance date from 240 days to 365 days after publication of a final rule based on this proposed rule, our labeling cost model suggests we could increase the percentages of required labeling changes coinciding with regularly scheduled labeling changes from 2 percent to about 4 percent, although it would not change the estimated small amount (10 percent) of paper inserts or 0 percent of packaging lost. This would reduce the one-time labeling costs by about $0.1 M.

IV. References

1. *"The Big Six" Hearing Aid Companies*. Hearing Loss Journal 2016; Available from: http://www.hearinglossjournal.com/the-big-six-hearing-aid-companies/.
2. Kochkin, S. *20Q: 25 Years of MarkeTrak - The Highlights*. Audiology Online 2012; Available from: http://www.audiologyonline.com/articles/20q-25-years-marketrak-highlights-6616.
3. Smith, A. and M. Anderson. *Online Shopping and E-Commerce*. Pew Research Center 2016; Available from: http://www.pewinternet.org/2016/12/19/online-shopping-and-e-commerce/.
4. Columbia Hearing Center. *How Long Do Hearing Aids Last?* 2013; Available from: https://columbiamohearingcenter.com/how-long-do-hearing-aids-last-and-how-to-extend-their-life/.
5. Blazer, D., S. Domnitz, and C. Liverman. *Hearing Health Care For Adults: Priorities for Improving Access and Affordability*. 2016; Available from: http://nap.edu/23446.
6. RTI International, *2014 FDA Labeling Cost Model. Final Report.* 2015.
7. Bureau of Labor Statistics. *Occupational Employment Statistics: May 2017 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 325400 – Pharmaceutical and Medical Manufacturing*. Available from: https://www.bls.gov/oes/current/naics4_325400.htm.

Appendix: Supplemental Analysis of the Potential Quality-of-Life Benefits of the Proposed Rule

In our main analysis, we estimate a range of monetary benefits of the proposed rule. These benefits are calculated as the net cost savings for existing hearing aid users wishing to buy lower cost hearing aids that are not bundled with professional services, accounting for the additional costs to users of products that convert to prescription medical devices. In addition to these effects, it is possible lower prices for hearing aids in states that currently restrict online hearing aid sales, combined with higher product visibility from hearing aids appearing in general retail outlets, as well as increased opportunity for impulse buying and buying hearing aids as gifts for other people, may result in quality-of-life benefits for additional users of hearing aid products with

perceived mild-to-moderate hearing loss when compared to a baseline of no regulatory action. There are at least two methods to value these potential benefits. In the method we discussed in the main analysis, we valued these potential health benefits, along with all other sources of consumer utility and disutility from hearing aids, using consumer revealed preferences for hearing aids themselves. In this appendix, we present a second method in which we value these benefits using methods that capture the maximum amount of money an individual would willingly exchange for the improvement in quality of life, taking into account the individual's reduced ability to consume other goods. This appendix describes a supplemental analysis of the potential quality-of-life benefits for these individuals.

The HHS *Guidelines for Regulatory Impact Analysis* (2016)[1] contain an approach to valuing morbidity reductions anticipated from regulatory actions. When high-quality direct willingness-to-pay estimates are not available for a morbidity risk reduction, analysts are directed to combine estimates of the Quality-Adjusted Life Year (QALY) gains of an intervention with estimates of the monetary value per QALY.

We derive our estimates for the QALY gains from Morris et al. (2012)[2], which reports utility gains expected from hearing aids in the context of a cost-effectiveness analysis of screening individuals between the ages of 60 and 70 for bilateral hearing loss of at least 35 dB HL. Their primary estimate of the utility gain from hearing aids is 0.068, with a sensitivity analysis range of 0.035 to 0.105. These estimates are derived from a

1 U.S. Department of Health and Human Services, Guidelines for Regulatory Impact Analysis. 2016. Available at https://aspe.hhs.gov/reports/guidelines-regulatory-impact-analysis.
2 Morris AE, Lutman ME, Cook AJ, Turner D. "An economic evaluation of screening 60- to 70-year-old adults for hearing loss." J Public Health (Oxf). 2013 Mar;35(1):139-46. doi: 10.1093/pubmed/fds058. Epub 2012 Sep 30. PMID: 23027734.

pair of studies measuring the improvement in quality of life, measured in utility. Davis et al. (2007)[3] reports estimates derived from the Health Utilities Index (HUI) and Short Form 6 Dimensions (SF-6D), while Barton et al. (2004)[4] reports estimates derived from the EQ-5D, HUI, and SF-6D. Since the utility gain estimates are from individuals newly identified as hearing impaired, and the decibel threshold of the screening corresponds with mild hearing loss, these estimates seem reasonable to apply to this analysis.

We convert the Morris et al. (2012) estimates of the utility gain from hearing aids to the present value of the QALY gains by assuming hearing aids last 5 years, and by discounting the stream of annual utility gains to the year of purchase using a 3 percent and a 7 percent discount rate. Table A1 reports the present value of the QALY gains implied for each estimate of the utility gain and for each discount rate. This correction is problematic if the QALY estimates are already multi-year PVs, which would further increase the size of the already large benefit estimates, a consideration we will investigate if we determine later the approach taken to valuing health benefits presented in this appendix is superior to the approach we used in the benefits section.

Table A1. Present Value of QALY Gain of Hearing Aid

Estimate of Utility Gain	QALY Gain	
	3%	7%
0.035	0.160	0.144
0.068	0.311	0.279
0.105	0.481	0.431

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) at HHS updates the Department's estimates of value per QALY annually, and has published

3 Davis A, Smith P, Ferguson M et al. "Acceptability, benefit and costs of early screening for hearing disability: a study of potential screening tests and methods." Health Technol Asses 2007;11(42): 1–294.
4 Barton G, Bankart J, Davis A et al. "Comparing utility scores before and after hearing aid provision: results according to the EQ-5d, HU13 and SF-6D." Appl Health Econ Health Policy 2004;3(2):103–5.

guidance (2021)[5] documenting the approach to updating these estimates for inflation, real income growth, and other factors. We assume the policy would take effect in 2022, and report monetized effects using expected real income levels for the same year. For reductions in morbidity occurring in 2022, ASPE recommends a central estimate of the value per QALY of $590,000 for analyses using a 3% discount rate and $980,000 for analyses using a 7% discount rate. Table A2 reports the value per QALY under both discount rates corresponding to a low, central, and high estimates of the Value Per Statistical Life (VSL). All monetary estimates are reported in 2020 dollars, for reductions in morbidity risks that begin in 2022.

Table A2. Value Per QALY in 2022 (Reported in 2020 Dollars)

Estimate	VSL	Value Per QALY	
		3% Discount Rate	7% Discount Rate
Low	$5,400,000	$280,000	$460,000
Central	$11,600,000	$590,000	$980,000
High	$17,600,000	$900,000	$1,500,000

Combining the estimates of the QALY gain of a hearing aid reported in Table A1 and the value per QALY estimates reported in Table A2, we monetize the value of the QALY gains per hearing aid user. Table A3 reports these values using a 3% discount rate and Table A4 reports these values using a 7% discount rate. All monetary estimates are reported in 2020 dollars, for reductions in morbidity risks that occur in 2022.

Table A3. Value of the QALY Gains Per User, 3% Discount Rate

Estimate of Utility Gain	Low VSL	Central VSL	High VSL
0.035	$44,000	$95,000	$144,000
0.068	$86,000	$184,000	$280,000

5 Office of the Assistant Secretary for Planning and Evaluation (ASPE). 2021. "Appendix D: Updating Value per Statistical Life (VSL) Estimates for Inflation and Changes in Real Income. Available at https://aspe.hhs.gov/reports/updating-vsl-estimates.

0.105	$132,000	$284,000	$432,000

Table A4. Value of the QALY Gains Per User, 7% Discount Rate

Estimate of Utility Gain	Low VSL	Central VSL	High VSL
0.035	$66,000	$141,000	$215,000
0.068	$128,000	$274,000	$417,000
0.105	$197,000	$423,000	$644,000

At this time, we are not including these monetary estimates of quality-of-life benefits associated with additional access to low-cost hearing aids because there is substantial uncertainty regarding the number of new users of hearing aids under the proposed rule. There is also substantial uncertainty regarding current use of PSAPs and the percentage of new users of hearing aids who may be current users of PSAPs. Finally, there is substantial uncertainty regarding the valuation of the potential health benefits for new users and the incremental change in health benefits for those who change devices or, more generally, regarding net changes in consumer utility from such devices including health benefits. The magnitude of the monetary value of the quality-of-life improvements per person we estimate exceeds the expected per-user cost of OTC hearing aids ($399) under all combinations of utility-gain estimates and the estimates of the value per QALY. This suggests that each additional hearing aid user, if the proposed rule were finalized, would experience significant net benefits, accounting for their quality-of-life improvements and the costs of the hearing aids.

If these estimates are multiplied by some estimate of new users without further adjustments, the resulting benefits estimates would likely be overstated for several reasons:

1. Selection among respondents to the HRQL survey. The estimates in Davis come from individuals screened for hearing loss, who both accepted, and reported using the hearing aids. We could not quickly identify the magnitude of the attrition from individuals fitted for a hearing aid but discontinued use in the first three months or otherwise left the sample. The paper acknowledges this limitation on page 113: "This poses a question as to whether this attrition in use of aids could have caused a bias in the findings of this study." One perhaps somewhat underdeveloped approach to numerically addressing this issue: adopt the Morris estimate of 66% who "Accept offer of hearing aid" and assign zero value to the remaining 34%. Therefore, a HUI estimate of 0.068 among individuals that accept and use hearing aids could be converted to 0.068*0.66 = 0.4488 utility gain among individuals offered a hearing aid. Similar adjustments could be made to the low and high range of the utility gain estimates.

2. Discontinued Use. The QALY estimates based on the utility scores assume continuous use for 5 years, but we may anticipate some individuals may discontinue use. Morris picks a primary estimate of 90% for the "Probability of using hearing aid in first 5 years," which falls to 62% for the "Probability of using hearing aid beyond first 5 years." We could linearly interpolate this such that the utility gain in year 1 is 90%; year 2, 84.4%; year 3, 78.8%; year 4, 73.2%; and year 5, 67.6%. Ignoring discounting, the QALY figure shrinks by the midpoint of 78.8% of the earlier reported estimates, slightly higher than when discounting.

3. Choice of HRQL measure. The Morris paper favors the HUI quality of life measures over the SF-6D measure, which is significantly lower (0.016 in the Davis paper). If the higher HUI measures showed up as benefit estimates in the main analysis,

it would be pretty straightforward to adopt the lower estimates based on SF-6D as a sensitivity analysis.

Combining issues 1 and 2 would roughly halve the QALY calculation, while using the lower SF-6D measure (combined with 1 and 2) would generate a QALY estimate roughly 10 percent of the unadjusted figure.

We note that the value of these quality-of-life improvements also far exceed the estimated cost of an economy-level hearing aid bundled with professional services purchased from a specialty retail outlet ($1,657), which generates certain issues with respect to observed consumer behavior. If these estimates of the subjective value of potential benefits consumers place on using hearing aids are accurate, one may reasonably have supposed they would have already tried hearing aids at a cost that amounts to a fraction of that value. One confounding issue is that many individuals with mild-to-moderate hearing loss may not realize they have measurable hearing loss, as indicated by the underlying source of our utility-gain estimates, or may not realize they may benefit from using hearing aids. Of course, with respect to uptake specifically, in such a situation it is unclear why a further drop in the price of hearing aids would cause such consumers to take them up. Another possibility is that there are substantial sources of consumer disutility associated with hearing aid use that must also be accounted for, which are issues accounted for in our primary method of valuing these potential net benefits for new users using observed market behavior.

We request comment on the following areas: (1) the appropriateness of the utility gain estimates and subjective consumer valuation based on revealed preferences estimates contained in this supplementary analysis and recommendations for additional sources for these estimates; (2) estimates of the incremental increase or decrease in health benefits from consumers who switch from existing hearing aid devices to OTC hearing aid devices or from PSAPs to OTC hearing aid devices; (3) estimates of the number of users expected to switch from existing hearing aid devices to OTC hearing aid devices and from PSAPs to OTC hearing aid devices as a result of the proposed rule; (4) estimates of the number of new users of hearing aids as a result of the proposed rule; and (5) information on the distribution by demographic group of new users of hearing aids and users expected to switch type of hearing aid or hearing technology as a result of the proposed rule.