Title 21

EDITORIAL NOTE ON PART 201

Editorial Note: Nomenc ature changes to part 201 appear at 69 FR 13717, Mar 24, 2004

§ 201.57 Specific requirements on content and format of labeling for human prescription drug and biological products described in § 201.56(b)(1).

The requ rements n th s sect on app y on y to prescr pt on drug products descr bed n § 201 56(b)(1) and must be mp emented accord ng to the schedu e spec fied n § 201 56(c), except for the requ rement n paragraph (c)(18) of th s sect on to repr nt any FDA-approved pat ent abe ng at the end of prescr pt on drug abe ng or accompany the prescr pt on drug abe ng, wh ch must be mp emented no ater than June 30, 2007

(a) ***Highlights of prescribing information.*** The fo ow ng nformat on must appear n a prescr pt on drug abe ng

(1) ***Highlights limitation statement.*** The verbat m statement "These h gh ghts do not nc ude a the nformat on needed to use (*insert name of drug product*) safe y and effect ve y See fu prescr b ng nformat on for (nsert name of drug product) "

(2) ***Drug names, dosage form, route of administration, and controlled substance symbol.*** The propr etary name and the estab shed name of the drug, f any, as defined n sect on 502(e)(3) of the Federa Food, Drug, and Cosmet c Act (the act) or, for b o og ca products, the proper name (as defined n § 600 3 of th s chapter) nc ud ng any appropr ate descr ptors Th s nformat on must be fo owed by the drug's dosage form and route of adm n strat on For contro ed substances, the contro ed substance symbo des gnat ng the schedu e n wh ch the contro ed substance s sted must be nc uded as requ red by § 1302 04 of th s chapter

(3) ***Initial U.S. approval.*** The verbat m statement " n t a U S Approva " fo owed by the four-d g t year n wh ch FDA n t a y approved a new mo ecu ar ent ty, new b o og ca product, or new comb nat on of act ve ngred ents The statement must be p aced on the ne mmed ate y beneath the estab shed name or, for b o og ca products, proper name of the product

(4) ***Boxed warning.*** A conc se summary of any boxed warn ng requ red by paragraph (c)(1) of th s sect on, not to exceed a ength of 20 nes The summary must be preceded by a head ng, n upper-case etters, conta n ng the word "WARN NG" and other words that are appropr ate to dent fy the subject of the warn ng The head ng and the summary must be conta ned w th n a box and bo ded The fo ow ng verbat m statement must be p aced mmed ate y fo ow ng the head ng of the boxed warn ng "See fu prescr b ng nformat on for comp ete boxed warn ng "

(5) ***Recent major changes.*** A st of the sect on(s) of the fu prescr b ng nformat on, m ted to the abe ng sect ons descr bed n paragraphs (c)(1), (c)(2), (c)(3), (c)(5), and (c)(6) of th s sect on, that conta n(s) substant ve abe ng changes that have been approved by FDA or author zed under § 314 70(c)(6) or (d)(2), or § 601 12(f)(1) through (f)(3) of th s chapter The head ng(s) and, f appropr ate, the subhead ng(s) of the abe ng sect on(s) affected by the change must be sted together w th each sect on's dent fy ng number and the date (month/year) on wh ch the change was ncorporated n abe ng These abe ng sect ons must be sted n the order n wh ch they appear n the fu prescr b ng nformat on A changed sect on must be sted under th s head ng n H gh ghts for at east 1 year after the date of the abe ng change and must be removed at the first pr nt ng subsequent to the 1 year per od

(6) ***Indications and usage.*** A conc se statement of each of the product's nd cat ons, as requ red under paragraph (c)(2) of th s sect on, w th any appropr ate subhead ngs Major m tat ons of use (e g , ack of effect n part cu ar subsets of the popu at on, or second ne therapy status) must be br efly noted f the product s a member of an estab shed pharmaco og c c ass, the conc se statement under th s head ng n H gh ghts must dent fy the c ass n the fo ow ng manner "(Drug) s a (name of c ass) nd cated for (nd cat on(s)) "

(7) ***Dosage and administration.*** A conc se summary of the nformat on requ red under paragraph (c)(3) of th s sect on, w th any appropr ate subhead ngs, nc ud ng the recommended dosage reg men, start ng dose, dose range, cr t ca d fferences among popu at on subsets, mon tor ng recommendat ons, and other c n ca y s gn ficant c n ca pharmaco og c nformat on

(8) ***Dosage forms and strengths.*** A conc se summary of the nformat on requ red under paragraph (c)(4) of th s sect on, w th any appropr ate subhead ngs (e g , tab ets, capsu es, njectab e, suspens on), nc ud ng the strength or potency of the dosage form n metr c system (e g , 10-m gram tab ets) and whether the product s scored

(9) ***Contraindications.*** A conc se statement of each of the product's contra nd cat ons, as requ red under paragraph (c)(5) of th s sect on, w th any appropr ate subhead ngs

(10) ***Warnings and precautions.*** A conc se summary of the most c n ca y s gn ficant nformat on requ red under paragraph (c)(6) of th s sect on, w th any appropr ate subhead ngs, nc ud ng nformat on that wou d affect dec s ons about whether to prescr be a drug,

(11) ***Adverse reactions.***

( ) A st of the most frequent y occurr ng adverse react ons, as descr bed n paragraph (c)(7) of th s sect on, a ong w th the cr ter a used to determ ne nc us on (e g , nc dence rate) Adverse react ons mportant for other reasons (e g , because they are ser ous or frequent y ead to d scont nuat on or dosage adjustment) must not be repeated under th s head ng n H gh ghts f they are nc uded e sewhere n H gh ghts (e g , Warn ngs and Precaut ons, Contra nd cat ons)

( ) For drug products other than vacc nes, the verbat m statement "To report SUSPECTED ADVERSE REACT ONS, contact (*insert name of manufacturer*) at (*insert manufacturer s phone number*) or FDA at (*insert current FDA phone number and Web address for voluntary reporting of adverse reactions*) "

( ) For vacc nes, the verbat m statement "To report SUSPECTED ADVERSE REACT ONS, contact (*insert name of manufacturer*) at (*insert manufacturer s phone number*) or VAERS at (*insert the current VAERS phone number and Web address for voluntary reporting of adverse reactions*) "

(v) For manufacturers w th a Web s te for vo untary report ng of adverse react ons, the Web address of the d rect nk to the s te

(12) ***Drug interactions.*** A conc se summary of the nformat on requ red under paragraph (c)(8) of th s sect on, w th any appropr ate subhead ngs

(13) ***Use in specific populations.*** A conc se summary of the nformat on requ red under paragraph (c)(9) of th s sect on, w th any appropr ate subhead ngs

(14) ***Patient counseling information statement.*** The verbat m statement "See 17 for Pat ent Counse ng nformat on" or, f the product has FDA-approved pat ent abe ng, the verbat m statement "See 17 for Pat ent Counse ng nformat on and (nsert e ther FDA-approved pat ent abe ng or Med cat on Gu de) "

(15) ***Revision date.*** The date of the most recent rev s on of the abe ng, dent fied as such, p aced at the end of H gh ghts

(b) ***Full prescribing information: Contents.*** Contents must conta n a st of each head ng and subhead ng requ red n the fu prescr b ng nformat on under § 201 56(d)(1), f not om tted under § 201 56(d)(4), preceded by the dent fy ng number requ red under § 201 56(d)(1) Contents must a so conta n any add t ona subhead ng(s) nc uded n the fu prescr b ng nformat on preceded by the dent fy ng number ass gned n accordance w th § 201 56(d)(2)

(c) ***Full prescribing information.*** The fu prescr b ng nformat on must conta n the nformat on n the order requ red under paragraphs (c)(1) through (c)(18) of th s sect on, together w th the head ngs, subhead ngs, and dent fy ng numbers requ red under § 201 56(d)(1), un ess om tted under § 201 56(d)(4) f add t ona subhead ngs are used w th n a abe ng sect on, they must be preceded by the dent fy ng number ass gned n accordance w th § 201 56(d)(2)

(1) ***Boxed warning.*** Certa n contra nd cat ons or ser ous warn ngs, part cu ar y those that may ead to death or ser ous njury, may be requ red by the FDA to be presented n a box The boxed warn ng ord nar y must be based on c n ca data, but ser ous an ma tox c ty may a so be the bas s of a boxed warn ng n the absence of c n ca data The box must conta n, n uppercase etters, a head ng ns de the box that nc udes the word "WARN NG" and conveys the genera focus of the nformat on n the box The box must br efly exp a n the r sk and refer to more deta ed nformat on n the "Contra nd cat ons" or "Warn ngs and Precaut ons" sect on, accompan ed by the dent fy ng number for the sect on or subsect on conta n ng the deta ed nformat on

(2) ***1 Indications and usage.*** Th s sect on must state that the drug s nd cated for the treatment, prevent on, m t gat on, cure, or d agnos s of a recogn zed d sease or cond t on, or of a man festat on of a recogn zed d sease or cond t on, or for the re ef of symptoms assoc ated w th a recogn zed d sease or cond t on

( ) Th s sect on must nc ude the fo ow ng nformat on when the cond t ons sted are app cab e

(A) f the drug s used for an nd cat on on y n conjunct on w th a pr mary mode of therapy (e g , d et, surgery, behav or changes, or some other drug), a statement that the drug s nd cated as an adjunct to that mode of therapy

(B) f ev dence s ava ab e to support the safety and effect veness of the drug or b o og ca product on y n se ected subgroups of the arger popu at on (e g , pat ents w th m d d sease or pat ents n a spec a age group), or f the nd cat on s approved based on a surrogate endpo nt under § 314 510 or § 601 41 of th s chapter, a succ nct descr pt on of the m tat ons of usefu ness of the drug and any uncerta nty about ant c pated c n ca benefits, w th reference to the "C n ca Stud es" sect on for a d scuss on of the ava ab e ev dence

(C) f spec fic tests are necessary for se ect on or mon tor ng of the pat ents who need the drug (e g , m crobe suscept b ty tests), the dent ty of such tests

(D) f nformat on on m tat ons of use or uncerta nty about ant c pated c n ca benefits s re evant to the recommended nterva s between doses, to the appropr ate durat on of treatment when such treatment shou d be m ted, or to any mod ficat on of dosage, a conc se descr pt on of the nformat on w th reference to the more deta ed nformat on n the "Dosage and Adm n strat on" sect on

(E) f safety cons derat ons are such that the drug shou d be reserved for spec fic s tuat ons (e g , cases refractory to other drugs), a statement of the nformat on

(F) f there are spec fic cond t ons that shou d be met before the drug s used on a ong term bas s (e g , demonstrat on of respons veness to the drug n a short term tr a n a g ven pat ent), a statement of the cond t ons; or, f the nd cat ons for ong term use are d fferent from those for short term use, a statement of the spec fic nd cat ons for each use

( ) f there s a common be ef that the drug may be effect ve for a certa n use or f there s a common use of the drug for a cond t on, but the preponderance of ev dence re ated to the use or cond t on shows that the drug s neffect ve or that the therapeut c benefits of the product do not genera y outwe gh ts r sks, FDA may requ re that th s sect on state that there s a ack of ev dence that the drug s effect ve or safe for that use or cond t on

( ) Any statements compar ng the safety or effect veness of the drug w th other agents for the same nd cat on must, except for b o og ca products, be supported by substant a ev dence der ved from adequate and we -contro ed stud es as defined n § 314 126(b) of th s chapter un ess th s requ rement s wa ved under § 201 58 or § 314 126(c) of th s chapter For b o og ca products, such statements must be supported by substant a ev dence

(v) For drug products other than b o og ca products, a nd cat ons sted n th s sect on must be supported by substant a ev dence of effect veness based on adequate and we -contro ed stud es as defined n § 314 126(b) of th s chapter un ess the requ rement s wa ved under § 201 58 or § 314 126(c) of th s chapter nd cat ons or uses must not be mp ed or suggested n other sect ons of the abe ng f not nc uded n th s sect on

(v) For b o og ca products, a nd cat ons sted n th s sect on must be supported by substant a ev dence of effect veness nd cat ons or uses must not be mp ed or suggested n other sect ons of the abe ng f not nc uded n th s sect on

(3) ***2 Dosage and administration.***

( ) Th s sect on must state the recommended dose and, as appropr ate

(A) The dosage range,

(B) An upper m t beyond wh ch safety and effect veness have not been estab shed, or beyond wh ch ncreas ng the dose does not resu t n ncreas ng effect veness,

(C) Dosages for each nd cat on and subpopu at on,

(D) The nterva s recommended between doses,

(E) The opt ma method of t trat ng dosage,

(F) The usua durat on of treatment when treatment durat on shou d be m ted,

(G) Dos ng recommendat ons based on c n ca pharmaco og c data (e g , c n ca y s gn ficant food effects),

(H) Mod ficat on of dosage needed because of drug nteract ons or n spec a pat ent popu at ons (e g , n ch dren, n ger atr c age groups, n groups defined by genet c character st cs, or n pat ents w th rena or hepat c d sease),

( ) mportant cons derat ons concern ng comp ance w th the dosage reg men,

(J) Efficac ous or tox c concentrat on ranges and therapeut c concentrat on w ndows of the drug or ts metabo tes, f estab shed and c n ca y s gn ficant nformat on on therapeut c drug concentrat on mon tor ng (TDM) must a so be nc uded n th s sect on when TDM s necessary

( ) Dos ng reg mens must not be mp ed or suggested n other sect ons of the abe ng f not nc uded n th s sect on

( ) Rad at on dos metry nformat on must be stated for both the pat ent rece v ng a rad oact ve drug and the person adm n ster ng t

(v) Th s sect on must a so conta n spec fic d rect on on d ut on, preparat on (nc ud ng the strength of the fina dosage so ut on, when prepared accord ng to nstruct ons, n terms of m grams of act ve ngred ent per m ter of reconst tuted so ut on, un ess another measure of the strength s more appropr ate), and adm n strat on of the dosage form, f needed (e g , the rate of adm n strat on of parentera drug n m grams per m nute; storage cond t ons for stab ty of the reconst tuted drug, when mportant; essent a nformat on on drug ncompat b t es f the drug s m xed n v tro w th other drugs or d uents; and the fo ow ng verbat m statement for parentera s "Parentera drug products shou d be nspected v sua y for part cu ate matter and d sco orat on pr or to adm n strat on, whenever so ut on and conta ner perm t ")

(4) ***3 Dosage forms and strengths.*** Th s sect on must conta n nformat on on the ava ab e dosage forms to wh ch the abe ng app es and for wh ch the manufacturer or d str butor s respons b e, nc ud ng

( ) The strength or potency of the dosage form n metr c system (e g , 10 m gram tab ets), and, f the apothecary system s used, a statement of the strength n parentheses after the metr c des gnat on; and

( ) A descr pt on of the dent fy ng character st cs of the dosage forms, nc ud ng shape, co or, coat ng, scor ng, and mpr nt ng, when app cab e The Nat ona Drug Code number(s) for the drug product must not be nc uded n th s sect on

(5) ***4 Contraindications.*** Th s sect on must descr be any s tuat ons n wh ch the drug shou d not be used because the r sk of use (e g , certa n potent a y fata adverse react ons) c ear y outwe ghs any poss b e therapeut c benefit Those s tuat ons nc ude use of the

r sk of be ng harmed by the drug and for whom no potent a benefit makes the r sk acceptab e Known hazards and not theoret ca poss b t es must be sted (e g , f severe hypersens t v ty to the drug has not been demonstrated, t shou d not be sted as a contra nd cat on) f no contra nd cat ons are known, th s sect on must state "None "

(6) ***5 Warnings and precautions.***

( ) ***General.*** Th s sect on must descr be c n ca y s gn ficant adverse react ons (nc ud ng any that are potent a y fata , are ser ous even f nfrequent, or can be prevented or m t gated through appropr ate use of the drug), other potent a safety hazards (nc ud ng those that are expected for the pharmaco og ca c ass or those resu t ng from drug/drug nteract ons), m tat ons n use mposed by them (e g , avo d ng certa n concom tant therapy), and steps that shou d be taken f they occur (e g , dosage mod ficat on) The frequency of a c n ca y s gn ficant adverse react ons and the approx mate morta ty and morb d ty rates for pat ents exper enc ng the react on, f known and necessary for the safe and effect ve use of the drug, must be expressed as prov ded under paragraph (c)(7) of th s sect on n accordance w th §§ 314 70 and 601 12 of th s chapter, the abe ng must be rev sed to nc ude a warn ng about a c n ca y s gn ficant hazard as soon as there s reasonab e ev dence of a causa assoc at on w th a drug; a causa re at onsh p need not have been defin te y estab shed A spec fic warn ng re at ng to a use not prov ded for under the " nd cat ons and Usage" sect on may be requ red by FDA n accordance w th sect ons 201(n) and 502(a) of the act f the drug s common y prescr bed for a d sease or cond t on and such usage s assoc ated w th a c n ca y s gn ficant r sk or hazard

( ) ***Other special care precautions.*** Th s sect on must conta n nformat on regard ng any spec a care to be exerc sed by the pract t oner for safe and effect ve use of the drug (e g , precaut ons not requ red under any other spec fic sect on or subsect on)

( ) ***Monitoring: Laboratory tests.*** Th s sect on must dent fy any aboratory tests he pfu n fo ow ng the pat ent's response or n dent fy ng poss b e adverse react ons f appropr ate, nformat on must be prov ded on such factors as the range of norma and abnorma va ues expected n the part cu ar s tuat on and the recommended frequency w th wh ch tests shou d be performed before, dur ng, and after therapy

(v) ***Interference with laboratory tests.*** Th s sect on must br efly note nformat on on any known nterference by the product w th aboratory tests and reference the sect on where the deta ed nformat on s presented (e g , "Drug nteract ons" sect on)

(7) ***6 Adverse reactions.*** Th s sect on must descr be the overa adverse react on profi e of the drug based on the ent re safety database For purposes of prescr pt on drug abe ng, an adverse react on s an undes rab e effect, reasonab y assoc ated w th use of a drug, that may occur as part of the pharmaco og ca act on of the drug or may be unpred ctab e n ts occurrence Th s defin t on does not nc ude a adverse events observed dur ng use of a drug, on y those adverse events for wh ch there s some bas s to be eve there s a causa re at onsh p between the drug and the occurrence of the adverse event

( ) ***Listing of adverse reactions.*** Th s sect on must st the adverse react ons that occur w th the drug and w th drugs n the same pharmaco og ca y act ve and chem ca y re ated c ass, f app cab e The st or sts must be preceded by the nformat on necessary to nterpret the adverse react ons (e g , for c n ca tr a s, tota number exposed, extent and nature of exposure)

( ) ***Categorization of adverse reactions.*** W th n a st ng, adverse react ons must be categor zed by body system, by sever ty of the react on, or n order of decreas ng frequency, or by a comb nat on of these, as appropr ate W th n a category, adverse react ons must be sted n decreas ng order of frequency f frequency nformat on cannot be re ab y determ ned, adverse react ons must be sted n decreas ng order of sever ty

(A) ***Clinical trials experience.*** Th s sect on must st the adverse react ons dent fied n c n ca tr a s that occurred at or above a spec fied rate appropr ate to the safety database The rate of occurrence of an adverse react on for the drug and comparators (e g , p acebo) must be presented, un ess such data cannot be determ ned or presentat on of comparator rates wou d be m s ead ng f adverse react ons that occurred be ow the spec fied rate are nc uded, they must be nc uded n a separate st ng f comparat ve rates of occurrence cannot be re ab y determ ned (e g , adverse react ons were observed on y n the uncontro ed tr a port on of the overa safety database), adverse react ons must be grouped w th n spec fied frequency ranges as appropr ate to the safety database for the drug (e g , adverse react ons occurr ng at a rate of ess than 1/100, adverse react ons occurr ng at a rate of ess than 1/500) or descr pt ve y dent fied, f frequency ranges cannot be determ ned For adverse react ons w th s gn ficant c n ca mp cat ons, the st ngs must be supp emented w th add t ona deta about the nature, frequency, and sever ty of the adverse react on and the re at onsh p of the adverse react on to drug dose and demograph c character st cs, f data are ava ab e and mportant

(B) ***Postmarketing experience.*** Th s sect on of the abe ng must st the adverse react ons, as defined n paragraph (c)(7) of th s sect on, that are dent fied from domest c and fore gn spontaneous reports Th s st ng must be separate from the st ng of adverse react ons dent fied n c n ca tr a s

( ) ***Comparisons of adverse reactions between drugs.*** For drug products other than b o og ca products, any c a m compar ng the drug to wh ch the abe ng app es w th other drugs n terms of frequency, sever ty, or character of adverse react ons must be based on adequate and we -contro ed stud es as defined n § 314 126(b) of th s chapter un ess th s requ rement s wa ved under § 201 58 or § 314 126(c) of th s chapter For b o og ca products, any such c a m must be based on substant a ev dence

(8) ***7 Drug interactions.***

( ) Th s sect on must conta n a descr pt on of c n ca y s gn ficant nteract ons, e ther observed or pred cted, w th other prescr pt on or over-the-counter drugs, c asses of drugs, or foods (e g , d etary supp ements, grapefru t ju ce), and spec fic pract ca nstruct ons for prevent ng or manag ng them The mechan sm(s) of the nteract on, f known, must be br efly descr bed nteract ons that are descr bed n the "Contra nd cat ons" or "Warn ngs and Precaut ons" sect ons must be d scussed n more deta under th s sect on Deta s of drug nteract on pharmacok net c stud es that are nc uded n the "C n ca Pharmaco ogy" sect on that are pert nent to c n ca use of the drug must not be repeated n th s sect on

( ) Th s sect on must a so conta n pract ca gu dance on known nterference of the drug w th aboratory tests

(9) ***8 Use in specific populations.*** Th s sect on must conta n the fo ow ng subsect ons

( ) ***8.1 Pregnancy.*** Th s subsect on of the abe ng must conta n the fo ow ng nformat on n the fo ow ng order under the subhead ngs "Pregnancy Exposure Reg stry," "R sk Summary," "C n ca Cons derat ons," and "Data"

(A) ***Pregnancy exposure registry.*** f there s a sc ent fica y acceptab e pregnancy exposure reg stry for the drug, contact nformat on needed to enro n the reg stry or to obta n nformat on about the reg stry must be prov ded fo ow ng the statement "There s a pregnancy exposure reg stry that mon tors pregnancy outcomes n women exposed to (*name of drug*) dur ng pregnancy."

(B) ***Risk summary.*** The R sk Summary must conta n r sk statement(s) based on data from a re evant sources (human, an ma , and/or pharmaco og c) that descr be, for the drug, the r sk of adverse deve opmenta outcomes (*i.e.,* structura abnorma t es, embryo-feta and/or nfant morta ty, funct ona mpa rment, a terat ons to growth) When mu t p e data sources are ava ab e, the statements must be presented n the fo ow ng order Human, an ma , pharmaco og c The source(s) of the data must be stated The abe ng must state the percentage range of ve b rths n the Un ted States w th a major b rth defect and the percentage range of pregnanc es n the Un ted States that end n m scarr age, regard ess of drug exposure f such nformat on s ava ab e for the popu at on(s) for wh ch the drug s abe ed, t must a so be nc uded When use of a drug s contra nd cated dur ng pregnancy, th s nformat on must be stated first n the R sk Summary When app cab e, r sk statements as descr bed n paragraphs (c)(9)( )(B)(*1*) and (*2*) of th s sect on must nc ude a cross-reference to add t ona deta s n the re evant port on of the "Data" subhead ng n the "Pregnancy" subsect on of the abe ng f data demonstrate that a drug s not system ca y absorbed fo ow ng a part cu ar route of adm n strat on, the R sk Summary must conta n on y the fo ow ng statement "(*Name of drug*) s not absorbed system ca y fo ow ng (route of adm n strat on), and materna use s not expected to resu t n feta exposure to the drug."

(*1*) ***Risk statement based on human data.*** When human data are ava ab e that estab sh the presence or absence of any adverse deve opmenta outcome(s) assoc ated w th materna use of the drug, the R sk Summary must summar ze the spec fic deve opmenta outcome(s); the r nc dence; and the effects of dose, durat on of exposure, and gestat ona t m ng of exposure f human data nd cate that there s an ncreased r sk for a spec fic adverse deve opmenta outcome n nfants born to women exposed to the drug dur ng pregnancy, th s r sk must be quant tat ve y compared to the r sk for the same outcome n nfants born to women who were not exposed to the drug but who have the d sease or cond t on for wh ch the drug s nd cated to be used When r sk nformat on s not ava ab e for women w th the d sease or cond t on for wh ch the drug s nd cated, the r sk for the spec fic outcome must be compared to the rate at wh ch the outcome occurs n the genera popu at on The R sk Summary must state when there are no human data or when ava ab e human data do not estab sh the presence or absence of drug-assoc ated r sk

(*2*) ***Risk statement based on animal data.*** When an ma data are ava ab e, the R sk Summary must summar ze the find ngs n an ma s and based on these find ngs, descr be, for the drug, the potent a r sk of any adverse deve opmenta outcome(s) n humans Th s statement must nc ude The number and type(s) of spec es affected, t m ng of exposure, an ma doses expressed n terms of human dose or exposure equ va ents, and outcomes for pregnant an ma s and offspr ng When an ma stud es do not meet current standards for nonc n ca deve opmenta tox c ty stud es, the R sk Summary must so state When there are no an ma data, the R sk Summary must so state

(*3*) ***Risk statement based on pharmacology.*** When the drug has a we -understood mechan sm of act on that may resu t n adverse deve opmenta outcome(s), the R sk Summary must exp a n the mechan sm of act on and the potent a assoc ated r sks

(C) ***Clinical considerations.*** Under the subhead ng "C n ca Cons derat ons," the abe ng must prov de re evant nformat on, to the extent t s ava ab e, under the head ngs "D sease-assoc ated materna and/or embryo/feta r sk," "Dose adjustments dur ng pregnancy and the postpartum per od," "Materna adverse react ons," "Feta /Neonata adverse react ons," and "Labor or de very"

(*1*) ***Disease-associated maternal and/or embryo/fetal risk.*** f there s a ser ous known or potent a r sk to the pregnant woman and/or the embryo/fetus assoc ated w th the d sease or cond t on for wh ch the drug s nd cated to be used, the abe ng must descr be the r sk

(*2*) ***Dose adjustments during pregnancy and the postpartum period.*** f there are pharmacok net c data that support dose adjustment(s) dur ng pregnancy and the postpartum per od, a summary of th s nformat on must be prov ded

(*3*) ***Maternal adverse reactions.*** f use of the drug s assoc ated w th a materna adverse react on that s un que to

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.